Appendix S

Interpretive Guidelines

for

Mammography Suppliers

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
S125	§494.50 Condition for coverage: General To be approved for payment for this benefit under the Medicare program, a supplier of screening mammography services must meet all the conditions set forth in this subpart with respect to all services furnished to Medicare beneficiaries.	§494.50 Guidelines: The Conditions for Coverage do not apply to diagnostic mammography services. A diagnostic mammogram is made to diagnose a specific complaint or medical problem already identified by the patient or the patient's attending physician. It is not required that all services furnished by a supplier be performed at the location where the screening mammography procedure is performed. For example, the X-ray processing portion of the screening mammography services may be performed at a hospital or an ambulatory care center and the interpreting physician services performed in the physician's office. However, the supplier is responsible for ensuring that all screening mammography services performed meet the Conditions for Coverage, whether those services are performed directly by employees of the supplier or are provided by other organizations or individuals with whom the supplier has a contract or other arrangement. Documentation must be available to demonstrate, at a minimum, compliance with personnel, personnel orientation, obtaining and preserving records, equipment, safety, and quality assurance standards in these regulations.
S126	§494.51 Conditions for coverage: Compliance with Federal, State, and local laws and regulations. The supplier of screening mammography services must comply with all applicable Federal, State, and local laws and regulations pertaining to radiological services and screening mammography services. This includes- (a) Licensure or registration of supplier; (b) Licensure or registration of personnel; (c) Licensure or registration of equipment; and	§494.51 Guidelines: State law permitting, it is possible for one individual to satisfy the requirements for the following positions: equipment operator (42 CFR 494.56); physician consultant (42 CFR 494.52); and interpreting physician (42 CFR 494.54). However, the equipment operator does not have to be a physician.
S127	(d) Compliance with health and safety requirements.	

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S128	§494.52 Condition for Coverage: Consultation with a qualified physician.	§494.52(a) Guidelines: The screening mammography supplier is responsible for ensuring that physician consultants, used through arrangement, comply with the regulations as if they were employed directly by the supplier. The physician consultant must meet the requirements for the interpreting physician specified in 42 CFR 494.54(a) and (b). When the physician consultant is not on the facility staff, there should be a written contract between the facility and the physician that clearly indicates the responsibilities of both.
	(a) Standard: Qualifications for the physician consultant.	
S129	The supplier has the basic responsibility for the overall quality of the screening mammography examination conducted in his or her facility.	
S130	In meeting this responsibility, the supplier must have available either on staff or through arrangement a physician consultant who is a licensed doctor of medicine or a licensed doctor of osteopathy who meets the requirements for the interpretation of the results of the screening mammography procedure as specified in §494.54.	
	(b) Standard: Physician consultant	§494.52 (b) Guidelines: The physician consultant's documentation may be in any format as long as the documentation clearly shows that the consultant performed each of the tasks. The documentation must show that the physician consultant observed at least the following procedures to determine if they are conducted in accordance with the facility's procedures manual (see 42 CFR 494.56(b)): positioning; technique factor selection; equipment quality control procedures; patient handling; and record keeping and reporting procedures. These procedures are to be observed for each operator. In the case of the quality control procedures, for a particular operator, the consultant need observe only those procedures assigned to that operator under 42 CFR 494.64(f). The physician consultant must observe each operator performing an actual procedure on
S131	The physician consultant must document in writing annually that-	
	(1) He or she has checked the procedural manuals,	
S132	has observed at least monthly the operators performance, and	

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S133	has determined that both are adequate	an actual patient at least monthly. Observation of the operators may be conducted at any site where the screening mammography equipment meets the screening mammography equipment standards. §494.52(b)(1) Probe: How does the physician consultant's documentation show that he or she has checked the procedures manuals and observed the operators' performance during an actual procedure on an actual patient?
S134	(2) He or she has verified that equipment and personnel meet applicable Federal, State, and local licensure and registration requirements and that they are performing properly;	
S135	(3) Safe operating procedures are used; and	§494.52(b)(3) Guideline: Safe operating procedures are primarily those established to meet the requirements of 42 CFR 494.62 and 42 CFR 494.56(b) (adequate shielding for patients, personnel, and facilities; operation of the equipment only from a shielded position; wearing of monitoring badges by all personnel; protection against electrical hazards). The safe operating procedures are those required by 42 CFR 494.56(b) and those procedures contained in procedure manuals. The physician consultant must verify that the safety procedures are actually followed. §494.52(b)(3) Probe: What sources are used to ensure that the procedures contained in the procedures manuals are consistent with recognized standards of professional practice? Did the facility use, for example, State regulatory requirements, private groups recognized as authorities in this area, or make modifications of recognized, authoritative procedures to meet local conditions?
S136	(4) All the other requirements of this subpart are being met.	§494.52(b)(4) Guideline: It is not sufficient, for documentation purposes, that a physician consultant make a self-contained, general statement that says all the requirements in this subpart are being met. Documentation should show specifically how the consultant has determined the supplier met each of the requirements in this subpart.
S137	§494.54 Condition for coverage: interpretation of the results of screening mammography procedures. The results of all screening mammography procedures must be	

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	interpreted by a physician who meet the following certification, experience, continuing education, and written report requirements:	
S138	(a) Standard: Board certification. The interpreting physician must- (1) Be certified by the American Board of Radiology or by the American Osteopathic Board of Radiology; or (2) Be certified as qualified to interpret the results of screening mammography procedures by an appropriate program, as determined by the Secretary, that assures the qualifications of the individual.	§494.54(a)(1) Guidelines: The American Board of Radiology (ABR) and the American Osteopathic Board of Radiology (AOBR), require a physician to pass all parts (i.e., not just the mammography part) of ABR's or AOBR's examinations to be certified. The ABR certifies physicians in several specialty areas of radiology. Certification in diagnostic radiology is the appropriate certification for physicians interpreting mammograms. The ABR and the American College of Radiology (ACR) are not the same. The ABR certifies individuals, but the ACR does not. The ACR has board certified individuals in its organization, and it accredits facilities. §494.54(a)(2) Guideline: Currently, the Secretary does not recognize certification programs other than those of the ABR and AOBR.
	(b) Standard: Experience and continuing education.	
	The interpreting physician must also-	
S139	(1) Have been reading the results of an average of 10 or more screening or diagnostic mammographies per work week in the 6 months prior to beginning mammography screening for Medicare beneficiaries;	§494.54(b)(1) Probe: What evidence does the facility have that its interpreting physician has been reading the results of an average of 10 or more screening or diagnostic mammographies per work week in the 6 months prior to beginning mammography screening for Medicare beneficaries?
S140	(2) Have successfully completed or taught a minimum of 40 hours of postgraduate instruction in mammography interpretation prior to beginning mammography screening for Medicare beneficiaries;	§494.54(b)(2) and (3) Guideline: "Postgraduate instruction and work" means training completed after the M.D. degree. This training could include completing instruction successfully in a radiology residency program, training in continuing medical education courses, and attending mammography seminars and conferences.

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S141	(3) Have successfully completed or taught a minimum of 15 hours of postgraduate work in mammography interpretation every 36 months after beginning mammography screening for Medicare beneficiaries; and	Since the Medicare screening mammography program began January 1, 1991, January 1, 1994 would be the earliest date a facility could be cited for noncompliance with 42 CFR 494.54(b)(3).
S142	(4) Continue to read the results of an average of 10 or more screening or diagnostic mammographies per work week while reading screening mammographies for Medicare beneficiaries.	§494.54(b)(4) Guideline: The "10 or more" results that must be read may include additional results read for Medicare beneficiaries. §494.54(b)(1-4) Probe: How does the supplier ensure and document that the interpreting physician(s) meet the regulatory requirements for experience and continuing education?
	(c) Standard: Written and signed report.	
	The interpreting physician must-	
S143	(1) Prepare and sign a written report on his or her interpretation of the results (that is, images or films) of the screening mammography procedure;	
S144	(2) Provide a copy of the written report and the original images or films to the patient's screening mammography supplier for inclusion in the patient's medical record; and §	§494.54(c)(2) Probes: How does the supplier ensure that it obtains both a written report/interpretation and original images or films from the interpreting physician on each patient? Are the original images labeled appropriately, i.e., name of beneficiary, date, and view?

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S145	(3) Provide a written statement to the patient, either through a referring physician or his or her designate, or, if a referring physician is not available, directly to the patient.	§494.54(c)(3) Guidelines: If the patient has a referring physician, the interpreting physician does not have to supply a written statement directly to the patient. The interpreting physician may provide this statement to the referring physician who can then provide it to the patient. "Through a referring physician or his or her designate" means that the statement written by the interpreting physician must be given to the patient by the referring physician or his or her designate. It does not mean that the referring physician provides the patient with only a verbal or written report in his/her own words based on the interpreting physician's written statement. The referring physician may provide additional interpretation or explanation of the statement if he or she wishes but this is not an alternative to giving a copy of the written statement to the patient. Since the regulations do not require an individual to have a physician's referral to receive a screening mammography examination, all patients may not have a referring physician. Patients who are not referred for a screening mammography by a physician must be given the interpreting physician's report by the interpreting physician. The written report under 42 CFR 494.54(c)(2) and the written statement referred to in 42 CFR 494.54(c)(3) may be combined into a single report. §494.54(c)(3) Probes: How does the supplier ensure that the interpreting physician complies with the requirements of 42 CFR 494.54(c)(3)? What actions has the supplier taken to inform the referring physician of his/her responsibility to transmit the interpreting physician's statement to the patient?
S146	The statement should be written in terms easily understood by a lay person.	
S147	The statement must describe the test results and the importance of the screening mammography to her ongoing health (including, if her results are positive, a description of the next steps), as well as her responsibility to share with any new physician or supplier of her next screening mammography the date and place of her previous screening mammography procedure.	
	The statement must record--	
S148	the date of the procedure,	
S149	the name of the facility providing the procedure,	
S150	the physician (if any) to whom the woman wants a copy to be sent, and must indicate that the original images or films are being provided to the screening mammography supplier, for inclusion in the woman's medical record.	

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S151	§494.56 Condition for coverage: Qualifications and orientation of technical personnel and retention of employee records.	
	(a) Standard: Qualifications of operators of screening mammography equipement.	
	Anyone operating screening mammography equipment must-	
S152	(1) Be licensed by the State to perform radiological procedures, or, in States that have no licensure requirements, be certified in radiography by the American Registry of Radiologic Technologists, the American Registry of Clinical Radiographic Technologists, or possess equivalent certification qualifications;	§ 494.56(a)(1) Guidelines: In those States without licensure requirements, anyone operating mammography equipment must be certified by either the American Registry of Radiologic Technologists or the American Registry of Clinical Radiographic Technologists. Equivalent certification qualifications have not been established by the Secretary.
S153	(2) Have successfully completed a program of formal training in radiologic technology in a school that meets the requirements of appendix A (Standards for Accreditation of Educational Programs for Radiographers) of 42 CFR part 75 or that is approved by the Council on Allied Health Education and Accreditation, or has had at least 5 years experience in performing radiologic procedures, and at least 1 year experience in performing screening mammography before January 1 1991; and	§494.56(a)(2) Guidelines: "Have successfully completed" means that the operator has documentation from a school that shows that the operator has successfully completed a program of formal training in radiologic technology. "Year of experience" means regular weekly employment for a typical work year. Because screening mammography is one type of radiologic procedure, the year performing screening mammography can be included as one of the five years experience in performing radiologic procedures. §494.56(a)(2) Probe: What evidence or documentation does the facility have to show that its equipment operators meet the experience requirement?

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S154	(3) Have completed successfully specialized training in mammographic positioning, compression, and technique factor settings prior to the time he or she begins performing screening mammographies for Medicare beneficiaries, and	§494.56(a)(3) Guideline: Specialized training in mammography, both initial and at 24 month intervals thereafter, may be obtained through either formal or on-the-job training programs. The training should include demonstrations and a practical evaluation by the instructor of the student's performance conducting breast positioning compression and technique factor settings on a normal range of patients. There must be documentation of the training including the business address of the trainer, a brief description of the training, the date and length of the training, and an evaluation of the student's performance, signed and dated by the instructor.
S155	completes this specialized training every 24 months thereafter.	
	(b) Standard: Personnel orientation.	§494.56(b) Guideline: "Members of the staff" include supplier employees and individuals who furnish services for the supplier under an arrangement or agreement. §494.56(b) Probes Are relevant documents and instructions included in the procedures manual consistent with standards of professional practice? How does the supplier ensure that all new staff complete the orientation program? How is the procedures manual kept current and staff oriented to new documents and instructions?
S156	The supplier of screening mammography services must have an orientation program for operators of mammography equipment based on a procedures manual that	
S157	is available to all members of the staff and that	
S158	incorporates relevant documents, and instructions concerning the following.	
S159	(1) Precautions to protect the operator of the equipment, the patient and individuals in the surrounding area from unnecessary exposure to radiation.	
S160	(2) Determination of the area that will receive the primary beam (breast positioning).	§494.56(b)(2) Probe: Does the procedures manual include information on positioning and X-ray dose for dense breasts or for breasts with implants?

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S161	(3) Pertinent information on compression, exposure levels, resolution, contrast, noise, examination identification, artifacts, and average glandular dose per view.	§494.56(b)(3) Guideline: "Examination identification" refers to procedures used to indicate what patient was imaged, when, where, and by whom the image was produced.
S162	(4) Employee responsibilites concerning the proper use of personal radiation monitors.	§494.56(b)(4) Guideline: The "responsibilities" covered in the manual should include: o Who wears the monitors, when and where; o How often the monitors are read; o Who reads the monitors; o Who keeps employee exposure records; and o What actions are taken when exposure levels are too high.
S163	(5) Proper use and maintenance of equipment, including a discussion of the image receptors appropriate for use with mammography and the kV-target-filter combination to be used with each image receptor.	
S164	(6) Proper maintenance of records.	
S165	(7) Possible technical problems and solutions.	
S166	(8) Protection against electrical hazards.	
S167	(9) Hazards of excessive exposure to radiation.	

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S168	(c) Standard: Qualifications of individuals furnishing diagnostic X-Ray physics support. Individuals furnishing diagnostic X-ray physics support must meet one of the following qualifications. (1) The individual must be certified by the American Board of Radiology as a diagnostic medical physicist or possess equivalent qualifications. Additionally, the individual must meet minimum training, experience, and continuing education requirements pertinent to screening mammography. (2)The individual must be recognized by a State radiation control agency as qualified to provide oversight of the establishment and conduct of the quality assurance program in §494.64 which sets forth the standards of a quality assurance program for screening mammography required as a condition of coverage.	§494.56(c)(1) Guidelines: This requirement permits individuals to provide physics support if their qualifications related to diagnostic radiology are equivalent to those possessed by an ABR certified physicist. However, the term "equivalent qualifications" has not been established in regulations. For any individual, regardless of his/her certification status, the physicist should meet the following recommended, but not required, training and experience requirements pertinent to screening mammography: 1 Have at least 3 years of experience providing physics support to mammography facilities; or 2 Have undertaken or conducted a formal or on-the-job training program of at least 40 hours conducted by a physicist who meets the requirements of 42 CFR 494.56(c), and which includes coverage of: - Quality assurance procedures to meet the requirements of 42 CFR 494.64; - Instrument calibration requirements for X-ray beam qualities used in mammography; and - Image quality evaluation appropriate for mammography including the selection of appropriate image receptors, film processing requirements, phantom image evaluations; and - demonstrated proficiency in these skills under the supervision of a physicist who meets - the requirements of 42 CFR 494.56(c) or who has conducted evaluations of proficiency of other physicists. Additionally, physicists who have initially qualified by option 1 or 2 above should complete or conduct formal or on-the-job continuing education in any of the above areas every two years after beginning to provide this service for certified facilities. There must be documentation of all initial or continuing education training. This documentation, at a minimum, should include a brief description of the training, including the date and length, an evaluation of the student's performance signed by the instructor, and the business address of the supplier of the training.

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		§494.56(c)(2) Guidelines "Recognized by a State" means that if an individual is recognized by any State as qualified, he or she is qualified for purposes of this requirement to perform X-ray physics support in all States except in those whose laws or regulations preclude the individual from doing so. State recognition varies from State to State. In some States, an individual has to meet State standards. In other States, individuals are recognized if they meet the standards of professional groups such as the ABR or the American Board of Health Physicists. Review the documentation of individuals in a State that does not have its own standards to ensure that the individual meets the standards of the particular group(s) that the State accepts.
S169	(d) Standard: Employee records. Records are maintained to show that each employee is qualified for his or her position by means of appropriate State licensure, other certification, training, and experience.	
S170	§494.58 Condition for coverage: Obtaining and preserving records. The supplier of the current examination must make all reasonable efforts to obtain the beneficiary's recent screening mammography records, including original images and films, copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous screening mammographies that might be available from others, for comparison with the current screening mammography records.	§494.58 Probes: How does the supplier demonstrate that it routinely makes reasonable efforts to obtain the beneficiary's recent screening mammography records? What methods do the supplier use to assure adequate storage and retrieval of records of women examined in its facility (images and reports), for the required minimum 60 month period? What procedures are followed in answering requests for the records of women previously examined at the supplier's facility who are now being examined at a second facility? How often are such requests received?
	Records of previous screening mammographies obtained and of	

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	current and subsequent screening mammographies performed by the supplier must --	
S171	be properly preserved and	
S172	made available to other qualified mammography suppliers or others that submit a written request authorized by the beneficiary.	
	(a) Standard: Records of screening mammography services performed by the supplier.	§494.58(a) Guidelines: Records must be made available to you during the course of the survey, if requested.
S173	The supplier must make, for each beneficiary, a record of the screening mammography services it provides,	
	including-	
S174	(1) The date the screening mammography procedure was performed and the date of the interpretation;	
S175	(2) The name of the beneficiary;	
S176	(3) The name of the operator of the equipment and the name of the interpreting physician;	§494.58(a)(3) Guideline: Use of the operator's initials rather than his/her name is not acceptable.
S177	(4) A description of the procedures performed;	

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S178	(5) The name of the referring physician (if any), or other physician (if any) identified by the beneficiary to receive the interpreting physician's written report; and	
S179	(6) The date the physician's written report was sent to the appropriate physician or beneficiary.	
	(b) Standard: Preservation of records.	
S180	The supplier must provide satisfactory assurances (as documented in its medical records) that the images or films of the first and subsequent screening mammography procedures and the related written reports of the physicians' interpretations for each beneficiary are either placed in her medical record kept by the supplier or sent to another person (including the beneficiary) for placement in the beneficiary's medical record as directed by her or by her physician.	§494.58(b) Probe: What evidence exists that images or films and related written reports are being properly preserved?
S181	If the records of the examination must be retained by the supplier, they must be retained for a period of at least 60 calendar months following the date of service (or longer if required by State law).	
S182	If the supplier should cease to exist before the end of the	

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	60-month period, the records must be transferred to the woman or her primary care provider.	
S183	§494.60 Condition for coverage: Equipment standards. The equipment used to perform mammography must meet the following standards:	§494.60 Guideline: In general, if the manufacturer (or assembler) identifies the equipment as being limited to mammography use or meets the specifications accepted by the ACR Mammography Accreditation Program (MAP), consider it specifically designed for mammography. Typically, any system specifically designed for use with film-screen image receptors contains a special thin window X-ray tube, a molybdenum target, and a molybdenum filter and is designed to operate at low kilovoltage. There must also be dedicated compression and positioning apparatus.
S184	(a) Standard: Equipment design. The equipment must be specifically designed for mammography.	§494.60(a) Guideline: For purposes of these regulations, do not consider xeroxgraphy image receptors as designed specifically for screening mammography. Guidelines for 42 CFR 494.60(c) through 42 CFR 494.60(f) define current technology in screening mammography equipment.
S185	(b) Standard: FDA standards. The equipment must meet the FDA performance standards for diagnostic X-ray systems and their major components at 21 CFR 1020.30 and FDA's standards for radiographic equipment at 21 CFR 1020.31.	§494.60(b) Guideline: Equipment that meets FDA standards has a label or tag indicating this permanently affixed to the equipment. Mammographic X-ray systems manufactured before August 1, 1974, and image receptor support devices for mammographic X-ray systems manufactured before September 5, 1978, are exempt from FDA standards. This exempted equipment does not have the label but is still considered as meeting this standard. There will be few, if any, systems specifically designed for mammography dating before 1978. In the case of "mixed systems", (those in which new components manufactured after August 1, 1974, or September 5, 1978, are installed into equipment manufactured before these dates), only the new components are labeled as meeting FDA standards. As before, the older parts of the system are considered as meeting this HCFA standard.
S186	(c) Standard: Image receptor systems. The image receptor systems and all their individual components must be designed appropriately for mammography.	§494.60(c) Guideline: The manufacturer must identify image receptor systems as intended for mammography or such systems must meet the specifications accepted by the American College of Radiology MAP. Films must match the phosphorescent screen, e.g., orthochromatic films are used with green light emitting rare-earth screens and single emulsion film is used with single screen cassettes.

<table>
<tr><th>TAG NUMBER</th><th>REGULATION</th><th>GUIDANCE TO SURVEYORS</th></tr>
<tr><td>S187</td><td>(d) Standared: Developer Temperature. The developer temperature of the photographic processor is equivalent to that specified in writing by the film manufacturer for the particular film-developer-processer-development time combination.</td><td>§494.60(d) Guideline:

If the facility is not using the film manufacturer's specific recommendations, check its procedures manual in order to determine the procedure the facility uses to demonstrate that its processing techniques are equivalent to the manufacturer's recommendations. Equivalency may be demonstrated by comparing a film developed with the processing specifications the facility is using with film developed using the film manufacturer's processing specifications. If the supplier can demonstrate that key image quality measures (such as the optical density of a specific sensitometric step, contrast, and speed of the film developed using the facility's specifications are the same or better than those of the film devloped with the manufacturer's specifications) then, consider the processing equivalent to the film manufacturer's recommendations.</td></tr>
<tr><td>S188</td><td>(e) Standard; kV-target-filter combinations. The equipment must be limited to providing kV-targer-filter combinations appropriate to image receptors meeting the requirements of paragraph (c) of this section.</td><td>§494.60(e) Guidelines:

For Medicare purposes, the source assembly for systems using film-screen image receptors must have a beryllium window, molybdenum target, and molybdenum filter. The generator must not operate above 35kVp or below 23 kVp. W targets with A1 filters are not used with screen-film image receptors. Accept exceptions to this requirement if the facility can demonstrate current compliance with ACR's MAP image quality and dose standards.</td></tr>
<tr><td>S189</td><td>(f) Standard: Focal spot size. The focal spot size and source-to-image receptor distance combinations are limited to those appropriate for mammography.</td><td rowspan="2">§494.60(f) Guideline:

Focal spot size and source-to-image receptor distance (SID) combinations in the ranges shown on the table below are acceptable.

SID — Nonminal Focal Spot Size

>65 cm — < or = to 0.6 mm
51 to 65 cm — < or = to 0.5 mm
< or = to 50 cm — < or = to 0.4 mm

Do not measure the focal spot size. Obtain the nominal size from the information provided to the user by the manufacturer/assembler or by the physicist.</td></tr>
<tr><td>S190</td><td>(g) Standard: Devices to immobilize and compress the breast. Devices parallel to the</td></tr>
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	imaging plane must be available to immobilize and compress the breast.	
S191	(h) Standard: Anti-scatter grids. The equipment must have the capability for using anti-scatter grids.	§494.609(h) Guideline: The manufacturer designates anti-scatter grids designed for mammography. The "capability for using anti-scatter grids" means that the grids are immediately available to use during a specific procedure if necessary.
S192	(i) Standard: Automatic exposure control. The equipment must have the capability of automatic exposure	§494.60(i) Guideline: Automatic exposure control (AEC) is a feature that automatically terminates exposures to give appropriate optional densities for the particular patient's breast thickness and composition and for the screen-film systems and processing conditions used by the site for mammography. The AEC option should be selectable and in working order for each unit used for screening mammography.
S193	(j) Standard: Control panel indicators. The equipment must have a device (usually a milliammeter) or means for an audible signal to give positive indication of the production of X-rays whenever the X-ray tube is energized. The control panel must include appropriate indicators (labeled control settings or meters that show the physical factors such as kilovoltage potential (kVp), milliampere seconds (mAs), exposure time, or whether timing is automatic) used for exposure.	
S194	(k) Standard: Recalibration of mobile units. For mobile units and vans (or other mobile screening units) a phantom image	§494.60(k) Guideline: Discuss with the supplier how recalibration of mobile units occurs following relocation and how it monitors this activity. Continue the discussion until you are sure that

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	must be made after each relocation of the mobile unit or van. Equipment must be recalibrated as necessary to maintain quality of phantom image.	this regulatory requirement is met. Review any documentation that the supplier might provide. §494.60(k) Probes: How does the supplier ensure that the quality of the phantom image made after each relocation of the mobile unit or van is evaluated before further examinations are conducted? How does the supplier ensure the quality of the phantom image after each relocation of the mobile unit or van? What evidence exists that the supplier appropriately adjusts the equipment when the phantom image quality indicates it is necessary?
S195	§494.62 Condition for coverage: Safety standards. Screening mammograms must be conducted using equipment and operating procedures free of unnecessary hazards and providing minimum radiation exposure to patients, personnel, and other persons in the immediate environment.	
	(a) Standard: Safety Precautions.	§494.62(a) Guideline: Shielding standards must be in compliance with State law. In the absence of a State law, standards should meet the recommendations of the National Council on Radiation Protection and Measurements (NCRPM).
S196	Proper safety precautions must be maintained. This includes adequate shielding for patients, personnel, and facilities.	
S197	The equipment must be operable only from a shielded postion.	

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S198	(b) Standard: Exposure badges. Personnel operating the equipment must wear badges or other appropriate devices to measure their radiation exposure.	§494.62(b) Probes: How often are exposure records reviewed to determine if proper safety precautions are being maintained? What are the occupational exposure limits established by the facility, and what is their source (State law, NCRPM recommendations)? Have the exposure limits been exceeded since the last inspection and, if so, what actions were taken to correct the problem?
S199	(c) Standard: Equipment inspection. Periodic inspection of equipment and room shielding must be made by a staff or consultant medical physicist, by a physicist approved by an appropriate State or local government agency as meeting the qualification requirements of '494.56(c), or by a surveyor/inspector from a State or local government radiation control agency. Identified hazards must be promptly corrected.	§494.62(c) Guidelines: Perform inspection of radiation shielding when alterations of the facility or equipment, since the last inspection, change the shielding or operating position. This alteration may reduce shielding integrity and cause change in operator protection. Adding or removing walls, moving the operator's booth, moving equipment, and installing a new unit are examples of such alterations. When a screening mammography facilty uses an inspector from the State or local government radiation control agency for the periodic inspection of equipment and room shielding, that individual would not, based only on this inspection of the facility, meet the requirements for the person who has the overall responsibility for establishing and conducting the ongoing equipment quality assurance program under the direction of the physician consultant at 42 CFR 494.64(a). In addition, if a person from the State or local government radiation control agency conducts the inspection to enable the facility to comply with 42 CFR 494.62(c), he /she must not be the same surveyor used for the Medicare survey of the facility, unless the inspection was conducted to determine if the facility is in compliance with State or local radiation safety requirements.
S200	(d) Standard: Protection against electrical hazards. All equipment must be shockproof and grounded.	
S201	§494.64 Condition for coverage: Quality assurance. The supplier must have an equipment quality assurance	§494.64 Guidelines: The supplier has the basic responsibility for ensuring that there is an adequate quality assurance program even if the supplier hires a physics specialist to assist in

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	program specific to mammography imagery, and covering all components of the X-ray system, from the X-ray generator to the image developer, to ensure consistently high quality images with minimum patient exposure.	developing this program. In meeting this responsibility, the supplier's annual general review of the quality assurance program should address: o The qualifications of the person furnishing X-ray physics support; o Whether the program is specific to screening mammography; o Whether the program covers all components of the X-ray system; and o Whether the program ensures consistently high quality images with minimum patient exposure. §494.64 Probes: How does the supplier ensure that the quality assurance program is specific to mammography imagery? What individual(s) is responsible for conducting each of the necessary quality assurance activities including annual general review of the quality assurance program? What are their qualifications for their assignments? What is the process for conducting the annual general review of the quality assurance process? What is done with the results of the annual general review process?
S202	The supplier must conduct a general review of the program at least annually and	
S203	have available the services of a person qualified to furnish diagnostic X-ray physic support and capable of establishing and conducting the program.	
	(a) Standard: Responsibility for the quality assurance program.	§494.64(a) Guidelines:
S204	Under the direction of the physician consultant, the person furnishing diagnostic X-ray physics support has the overall responsibility for establishing and conducting the ongoing equipment quality assurance program.	The person supplying X-ray physics does not have to personally carry out all the routine tasks, (e.g., daily or monthly) identified in this section, but may train others to perform these duties. §494.64(a) Probes: How does the supplier identify individuals trained to conduct monitoring of equipment performance? What kinds of equipment have they been trained to monitor? If the X-ray physics support person arranges for corrective actions, equipment calibrations, or preventive

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	That individual's specific duties must include-	
S205	(1) Conducting or training others to conduct equipment performance monitoring functions;	
S206	(2) Analyzing the monitoring results to determine if there are any problems requiring correction; and	
S207	(3) Carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventive maintenance.	
	(b) Standard: Calibration of equipment. All variable parameters of the equipment must be calibrated-	§ 494.64(b) Guidelines: At a minimum, "calibration" means adjustment, when necessary, of the parameters of the device to bring them within the manufacturer's specifications. These procedures would, in general, be carried out by the manufacturer's representatives using the manufacturer's established protocols. The parameters that are included are: kVp, mA (or mAs) stations, timer settings, phototimer response, and any others specified in these protocols. Review the screening mammography supplier's records to ascertain that the calibrations are done. You are not expected to independently verify that the parameters are currently calibrated.
S208	(1) When the equipment is first installed;	
S209	(2) After any major changes or replacement of parts;	
S210	(3) At least annually during use; and	
S211	(4) When quality assurance tests indicate that calibration is needed.	
	(c) Standard: Performance monitoring.	

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S212	The supplier must routinely monitor the performance of the mammography system. (1) At a minimum, the parameters that must be monitored are-	
S213	(i) Processor performance (through) sensitometric-densitometric means);	
S214	(ii) Half value layer;	
S215	(iii) Output reproducibility and linearity;	
S216	(iv) Automatic exposure control reproducibility, kVp response, and thickness response;	
S217	(v) Adequacy of film storage (both before use and after exposure if processing does not occur immediately);	
S218	(vi) Availablity and use of technique charts that must include an indication of the kV-target-filter combination to be used with each image receptor;	§494.64(c)(1)(vi) Guideline: Routine performance monitoring of kV-target filter combinations is necessary with both mammography units with filters that automatically change depending upon the kV utilized and for those units with interlocks to protect against use of inappropriate manually selected filters, to assure that these functions continue to operate correctly. It is not intended that the kV itself be monitored on a daily or monthly basis. §494.64(c)(1)(vii) Probe: How does the screening mammography facility ensure darkroom integrity when film is processed/developed at locations other than the facility's own premise?
S219	(vii) Darkroom integrity;	

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S220	(viii) Image quality (using a testing device called a "Phantom", which simulates the composition of the breast and indicators of disease conditions allowing objectvie analysis of clinical image quality); and	§494.64(c)(1)(viii) Guideline: Only phantoms known to be adequate for objective analysis of clinical image quality should be used such as the RMI 152 and 156, the CIRS, the Nuclear Associates phantoms, and any others approved by the ACR mammography accreditation program. Phantoms that are not adequate for this purpose include the Kodak Pathe or ITO phantom.
S221	(ix) Dose.	§494.64(c)(1)(ix) Guideline: Dose is not measured directly, but it must be calculated from a measurement of exposure and applying mathematical factors obtained from standard references, (such as the "Handbook of Glandular Tissue Doses in Mammography" by Rosensten, Andersen, amd Warner (HHS Publication FDA 85-8239)). The dose to be calculated is defined in 42 CFR 494.64(d)(1).
	(2) The equipment must be monitored as follows:	
S222	(i) Processor performance and the use of a kV-target-filter combination appropriate to the image receptor must be monitored daily before patient irradiation.	§494.64(c)(2)(i) Guideline: For clarification of monitoring kV-target-filter combination, see guidelines for 42 CFR 494.64(c)(1)(vi).
S223	(ii) Image quality must be monitored with a phantom every time the unit is moved, altered in any major way including the replacement of parts, and at least monthly between movements or alterations.	§494.64(c)(2)(ii) Guidelines: Each time monitoring of image quality is required, such monitoring, including processing of the image and its evaluation and any necessary adjustments of the equipment to achieve proper performance, must be completed before patients are again exposed by the unit. This requirement is particularly important for mobile units. §494.64(c)(2)(ii) Probe: How does the supplier ensure and document that this requirement is met?

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<tr><th>TAG NUMBER</th><th>REGULATION</th><th>GUIDANCE TO SURVEYORS</th></tr>
<tr><td>S224</td><td>(iii) the frequency of monitoring all other parameters must be proportional to the expected variability of each parameter, but monitoring must be conducted at least annually</td><td rowspan="4">§494.64(c)(2) and (d)(1) Guidelines

Normally, monitoring frequency for each of the following should be no longer than the values given on the following table. Recommended standards of image quality are also given on the table. The surveyor is expected to measure phantom image quality and calculate dose from a measured exposure to confirm that they meet the desired standards of image quality. Determine if the other standards are met by checking the supplier's monitoring records.

<table>
<tr><th>ITEM</th><th>FREQUENCY</th><th>STDS OF IMAGE QUALITY</th></tr>
<tr><td>Processor Performance</td><td>Daily</td><td>Mid-density step and density difference(contrast) < + 0.1 OD of the optimized operating level and base + fog deviation ≤ 0.03 OD.</td></tr>
<tr><td>HVL</td><td>Annually</td><td>Meas. HVL with compression device in field ≥ (kVp/100) mmAl and ≤ (kVp/100 + 0.1 mm Al.</td></tr>
<tr><td>Output Reproducibility</td><td>Quarterly</td><td>Coefficient of variation ≤ 0.05 with 4 exposures at the same technique.</td></tr>
<tr><td>Output Linearity</td><td>Quarterly</td><td>mR/mAs values at any two consecutive tube current settings should not vary more than 0.1 times their sum.</td></tr>
<tr><td>Automatic Exposure Control Reproducibility</td><td>Annually</td><td>The phantom used for measurements related to this and the two following automatic control control parameters should be either acrylic or BR-12 and consist of at least three 2-cm-thick slabs to provide thicknesses of 2cm, 4cm, and 6cm (each having linear dimensions of at least 8 x 10 cm). When a fixed kVp is used to produce four images of the 4cm thick phantom, the maximum value for the coefficient of variation for exposure at the center of the image should be ≤ 0.05.</td></tr>
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</td></tr>
<tr><td></td><td>(d) Standard: Evaluation of monitoring results.</td></tr>
<tr><td>S225</td><td>Monitoring must be evaluated on a regular basis.</td></tr>
<tr><td>S226</td><td>(1) Standards of image quality giving acceptable ranges of values for each of the parameters tested must be established to aid in the evaluation. The standards of image quality related to dose must include a requirement that mean glandular dose for one craniocaudal view of a 4.5cm compressed breast (50 percent adipose/50 percent glandular) must not exceed 100, 300, and 400 mrad (millirad) for film/screen units without grids, film/screen units with grids, and xerography units, respectively. the</td></tr>
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<tr><th>ITEM</th><th>FREQUENCY</th><th>STDS OF IMAGE QUALITY</th></tr>
<tr><td>kVp Response of Automatic Exposure</td><td>Annually</td><td>Film density is maintained to ± 0.3 OD of the average optical density at the center of a exposure control phantom image over the range of kVp used in the facility. To obtain the average, at least four phantom images should be made, one each with the highest and lowest kVps commonly used in the facility and the other two at intermediate values.</td></tr>
<tr><td>Thickness Response of Automatic Exposure Control</td><td>Anually</td><td>Film density is maintained to ± 0.3 OD of the of average optical density at the center of a phantom image at each kVp commonly used in the facility. To obtain the average, images with phantom thicknesses of at least 2, 4, and 6 centimeters should be used.</td></tr>
<tr><td>Adequacy of Unexposed Film Storage</td><td>Quarterly</td><td>Increase in base + fog density over storage time is maintained to <0.02 OD.</td></tr>
<tr><td>Availability and Use of Technique Charts</td><td>Monthly</td><td>Ensure that charts are available and used.</td></tr>
<tr><td>kVp/target/filter Combination</td><td>Daily</td><td>Must be unchanged from that indicated on the technique charts.</td></tr>
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</td></tr>
<tr><td>S227</td><td>(2) The monitoring results must be compared routinely to the standards of image quality. If the results fall outside the acceptable range, the test must be repeated.</td><td></td></tr>
<tr><td>S228</td><td>If the results continue to be unacceptable, the source of the problem must be identified and corrected before further examinations are conducted.</td><td></td></tr>
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<tr><th>ITEM</th><th>FREQUENCY</th><th>STDS OF IMAGE QUALITY</th></tr>
<tr><td>Darkroom Integrity</td><td>Clean Daily Fog Measured When Bulbs or Filter Changed and Semi-annually</td><td>Minimum dust particles on film. Fog not greater than 0.1 OD with 2 minute test.</td></tr>
<tr><td>Phantom Image Quality</td><td>See §§94.64(c)(2)(ii)</td><td>Phantom image scores are not less than required by ACR MAP (currently specified only using RMI phantoms) and should not decrease more than one in any category between consecutive tests. Also they should not have decreased by more than one in any category from the intial baseline phantom image.</td></tr>
<tr><td>Dose</td><td>Annually</td><td>See 42 CFR 494.64(d)(1)</td></tr>
</table>
If the supplier can document that the item has remained within limits for at least three consecutive monitoring periods, it may use a longer monitoring interval for any parameters except processor performance and phantom image quality. In any case, the period should not be longer than one year.
</td></tr>
<tr><td>S229</td><td>(e) Standard: Retake analysis program. A program to analyze retakes must be established as a further aid in detecting and correcting problems affecting image quality or exposure.</td><td rowspan="2">§494.64(e) Guideline:

Ask the supplier to describe the retake analysis program the facility uses. Observe the method to verify that the procedure is used routinely, and ask for examples of implemented corrective actions as a result of the program. Note that the ACR recommends the analysis be done at least quarterly including at least 250 patients. Facilities with lower workloads would do this each time they reach this level of patient volume.

§494.64(e) Probe:

What is the retake analysis program used by the facility?</td></tr>
<tr><td>S230</td><td>(f) Standard: Responsible personnel. Responsibility for each standard, from monitoring through the annual review must be assigned to qualified personnel. These assignments must be documented in the supplier's records.</td></tr>
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APPENDIX T

INTERPRETIVE GUIDELINES

FOR

SWING BEDS

Surveyor Interpretive Guidelines for

Swing Beds

INDEX

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A500	**§482.66 Special requirements for hospital providers of long-term care services ("swing-beds").** A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from CMS to provide post-hospital extended care services, as specified in §409.30 of this chapter, and be reimbursed as a swing-bed hospital, as specified in §413.114 of this chapter: (a) Eligibility. A hospital must meet the following eligibility requirements:	Interpretive Guidelines §482.66 The swing-bed concept allows hospitals to use their beds interchangeably for either acute-care or post-acute care. This allows greater flexibility in meeting fluctuating needs of the patient. Compliance with eligibility standards is assessed prior to the survey.
A501	(1) The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see §413.24(d)(5) of this chapter).	
A502	(2) The hospital is located in a rural area. This includes all areas not delineated as "urbanized" areas on the most recent census.	
A503	(3) The hospital does not have in effect a 24-hour nursing waiver granted under §488.54(c) of this chapter.	
A504	(4) The hospital has not had a swing-bed approval terminated within the two years previous to application.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A505	(b) Skilled nursing facility services. The facility is substantially in compliance with the following skilled nursing facility requirements contained in subpart B of part 483 of this chapter. (1) Resident rights (§483.10(b)(3), (b)(4), (b)(5), (b)(6), (d), (e), (h), (i), (j)(1)(vii), (j)(1)(viii), (l), and (m)). (2) Admission, transfer, and discharge rights (§483.12(a)(1), (a)(2), (a)(3), (a)(4), (a)(5), (a)(6), and (a)(7)). (3) Resident behavior and facility practices (§483.13). (4) Patient activities (§483.15(f)). (5) Social services (§483.15(g)). (6) Discharge planning (§483.20(l)). (7) Specialized rehabilitative services (§483.45). (8) Dental services (§483.55).	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A508	§483.10 **Resident rights** The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following rights: (b) Notice of rights and services. (3) The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition;	Interpretive Guidelines §483.10 The intent of this requirement is to assure that each resident knows his or her rights and responsibilities and that the facility communicates this information prior to or upon admission, during the resident's stay, and when the facility's rules changes. A facility must promote the exercise of rights for all residents, including those who face barriers such as communication problems, hearing problems and cognition limits. These rights include the resident's right to: o Be informed about what rights and responsibilities the resident has (§483.10(b)(3 through 6)); o Choose a physician (§483.10(d)); o Participate in decisions about treatment and care planning (§483.10(d)); o Have privacy and confidentiality (§483.10(e)); o Work or not work (§483.10(h)); o Have privacy in sending and receiving mail (§483.10(i)); o Visit and be visited by others from outside the facility (§483.10(j)(1)(vii and viii)); o Retain and use personal possessions (§483.10(l)); and o Share a room with a spouse (§483.10(m)). Interpretive Guidelines §483.10(b)(3) "Total health status" includes functional status, medical care, nursing care, nutritional status, rehabilitation and restorative potential, activities potential, cognitive status, oral health status, psychosocial status, and sensory and physical impairments. Information on health status must be presented in language that the resident can understand. Communicating with the resident in language that the resident can understand includes minimizing the use of technical words, providing interpreters for non-English speaking residents, using sign language when needed, or other interventions, as appropriate. Survey Procedures and Probes §483.10(b)(3) Look for on-going efforts on the part of facility staff to keep residents informed. Look for evidence that information is communicated in a manner that is understandable to residents. Is information available when it is most useful to the residents such as when they are expressing concerns, raising questions, and on an on-going basis? Is there evidence in the medical record that the patient was informed of his rights, including the right to accept or refuse medical or surgical treatment?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A509	(4) The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive as specified in paragraph 8 of this section; and	Interpretive Guidelines §483.10(b)(4) "Treatment" is defined as care provided for purposes of maintaining/restoring health, improving functional level, or relieving symptoms. "Experimental research" is defined as development and testing of clinical treatments, such as an investigational drug or therapy, that involve treatment and/or control groups. For example, a clinical trial of an investigational drug would be experimental research. "Advance directive" means a written instruction, such as living will or durable power of attorney for health care, recognized under state law, relating to the provisions of health care when the individual is incapacitated. A resident who has the capacity to make a health care decision and who withholds consent to treatment or makes an explicit refusal of treatment either directly or through an advance directive, may not be treated against his/her wishes. The resident has the right to refuse to participate in experimental research. A resident being considered for participation in experimental research must be fully informed of the nature of the experiment and understand the possible consequences of participating. The opportunity to refuse to participate in experimental research must occur prior to the start of the research. Aggregated resident statistics that do not identify individual residents may be used for studies without obtaining resident permission. Survey Procedures and Probes §483.10(b)(4) If the facility participates in any experimental research involving residents, does it have an Institutional Review Board or other committee that reviews and approves research protocols? The requirement at §483.75(c) Relationship to Other HHC Regulations may apply, see 45 CFR Part 46, Protection of Human Subjects of Research). “Although these regulations at §483.75(c) are not in themselves considered requirements under this part, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds.”

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A509 (Cont.)		NOTE: 42 CFR §483.10(b)(8) containing advance directive requirements, guidelines, procedures and probes is contained below. 42 CFR §483.10(b)(8) The facility must comply with the requirements specified in Subpart I of Part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual's option, formulate an advance directive. This includes a written description of the facility's policies to implement advance directives and applicable State law. "Advance directive" means a written instruction, such as a living will or durable power of attorney for health care recognized under State law, relating to the provision of health care when the individual is incapacitated. Interpretive Guidelines §483.10(b)(8) This provision applies to residents admitted on or after December 1, 1991. The regulation at 42 CFR §489.102 specifies that at the time of admission of an adult resident, the facility must : o Maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care; o Provide written information concerning his or her rights under State law (whether statutory or recognized by the courts of the State) to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment, and the right to formulate advance directives; o Document in the resident's medical record whether or not the individual has executed an advance directive; o Not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive; o Ensure compliance with requirements of State law regarding advance directives; o Provide for educating staff regarding the facility's policies and procedures on advance directives; and o Provide for community education regarding issues concerning advance directives.

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A509 (Cont.)		The facility is not required to provide care that conflicts with an advance directive. In addition, the facility is also not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive, and state law allows the provider to conscientiously object. The sum total of the community education efforts must include a summary of the state law, the rights of residents to formulate advance directives, and the facility's implementation policies regarding advance directives. Video and audio tapes may be used in conducting the community education effort. Individual education programs do not have to address all the requirements if it would be inappropriate for a particular audience. Survey Procedures and Probes §483.10(b)(8) Review the records of sampled residents admitted on or after December 1, 1991, for facility compliance with advance directive notice requirements. o Determine to what extent the facility educates its staff regarding advance directives. o Determine to what extent the facility provides education for the community regarding individual rights under State law to formulate advance directives.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A510	(5) The facility must-- (i) Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of-- (A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged; (B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and (ii) Inform each resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of this section. (6) The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate.	Interpretive Guidelines: §483.10(b)(5-6) If payment is not made by Medicare or Medicaid for services, the provider must fully inform the resident of any related charges both at the time of admission and prior to the time that changes will occur in their bills. Listed below are general categories and examples of items and services that the facility may charge to resident funds, if they are requested and agreed to by a resident. o Telephone o Television/radio for personal use o Personal comfort items including smoking materials, notions, novelties, and confections o Cosmetic and grooming items and services in excess of those for which payment is made o Personal clothing o Personal reading matter o Gifts purchased on behalf of a resident o Flowers and plants o Social events and entertainment offered outside the scope of the activities program o Non-covered special care services such as privately hired nurses or aides o Private room, except when therapeutically required for example, isolation for infection control o Specially prepared or alternative food requested

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A511	(d) Free Choice. The resident has the right to-- (1) Choose a personal attending physician;	Interpretive Guidelines §483.10(d)(1) The right to choose a personal physician does not mean that the physician must serve the resident. If the physician of the resident's choosing fails to fulfill a given requirement, such as frequency of physician visits, the facility will have the right, after informing the resident, to seek alternate physician participation to assure provision of appropriate and adequate care and treatment. A facility may not place barriers in the way of residents choosing their own physician. If a resident does not have a physician, or if the resident's physician becomes unable or unwilling to continue providing care to the resident, the facility must assist the resident in exercising his/her choice in finding another physician. A resident can choose his/her own physician, but cannot have a physician who does not have swing bed admitting privileges. The requirement for free choice is met if a resident is allowed to choose a personal physician from among those who have practice privileges.
A512	(2) Be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well-being; and	Interpretive Guidelines §483.10(d)(2) "Informed in advance" means that the resident receives information necessary to make a health care decision. The information should include his/her medical condition, changes in his/her medical condition, the benefits and reasonable risks of the recommended treatment, and reasonable alternatives. If there are any financial costs to the resident in the treatment options, they should be disclosed in advance and in writing to the resident prior to his/her decision.

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A513	(3) Unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.	Interpretive Guidelines §483.10(d)(3) "Participates in planning care and treatment" means that the resident is afforded the opportunity to select from alternative treatments, to the level of his ability to understand. This applies both to initial decisions about care and treatment and to decisions about changes in care and treatment. The resident has the right to participate in care planning and to refuse treatment. Survey Procedures and Probes §483.10(d)(3) Look for evidence that the resident was afforded the right to participate in care planning or was consulted about care and treatment changes. If there appears to be a conflict between a resident's right and the resident's health or safety, determine if the facility attempted to accommodate both the exercise of the resident's rights and the resident's health, including exploration of care alternatives through a thorough care planning process in which the resident may participate. If a resident whose ability to make decisions about care and treatment is impaired, was he kept informed and consulted on personal preferences to the level of his ability to understand?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A514	(e) Privacy and confidentiality. The resident has the right to personal privacy and confidentiality of his or her personal and clinical records. Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident; (2) Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility; (3) The resident's right to refuse release of personal and clinical records does not apply when-- (i) The resident is transferred to another health care institution; or (ii) Record release is required by law.	Interpretive Guidelines §483.10(e) "Right to personal privacy" means that the resident has the right to privacy with whomever the resident wishes to be private and that this privacy should include both visual and auditory privacy. Private space may be created flexibly and need not be dedicated solely for visitation purposes. For example, privacy for visitation or meetings might be arranged by using a dining area between meals, a vacant chapel, office or room; or an activities area when activities are not in progress. Arrangements for private space could be accomplished through cooperation between the facility's administration and resident or family groups so that private space is provided for those requesting it without infringement on the rights of other residents. Facility staff must examine and treat residents in a manner that maintains the privacy of their bodies. A resident must be granted privacy when going to the bathroom and in other activities of personal hygiene. If an individual requires assistance, authorized staff should respect the individual's need for privacy. Only authorized staff directly involved in treatment should be present when treatments are given. People not involved in the care of the individual should not be present without the individual's consent while he/she is being examined or treated. Staff should pull privacy curtains, close doors, or otherwise remove residents from public view and provide clothing or draping to prevent unnecessary exposure of body parts during the provision of personal care and services. Survey Procedures and Probes §483.10(e) Document any instances where you observe a resident's privacy being violated. Completely document how the resident's privacy was violated. Documentation Example: Resident #12 left without gown or bed covers and unattended on 2B Corridor at 3:30 p.m. February 25, 2001. Identify the responsible party, if possible.

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A515	(h) Work. The resident has the right to-- (1) Refuse to perform services for the facility; (2) Perform services for the facility, if he or she chooses, when-- (i) The facility has documented the need or desire for work in the plan of care; (ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid; (iii) Compensation for paid services is at or above prevailing rates; and (iv) The resident agrees to the work arrangement described in the plan of care.	Interpretive Guidelines §483.10(h)(1)-(2) All resident work, whether of a voluntary or paid nature, must be part of the plan of care. A resident's desire for work is subject to medical appropriateness. As part of the plan of care, a therapeutic work assignment must be agreed to by the resident. The resident also has the right to refuse such treatment at any time that he or she wishes. At the time of development or review of the plan, voluntary or paid work can be negotiated. The "prevailing rate" is the wage paid to workers in the community surrounding the facility for the same type, quality, and quantity of work requiring comparable skills. Survey Procedures and Probes §483.10(h)(1)-(2) Are residents engaged in work (e.g., doing housekeeping, doing laundry, preparing meals)? Pay special attention to the possible work activities of residents with mental retardation or mental illness. If a resident is performing work, determine whether it is voluntary, and whether it is described in the plan of care. Is the work mutually agreed upon between the resident and the treatment team?
A516	(i) Mail. The resident has the right to privacy in written communications, including the right to-- (1) Send and promptly receive mail that is unopened; and (2) Have access to stationery, postage, and writing implements at the resident's own expense.	Interpretive Guidelines §483.10(i)(1)-(2) "Promptly" means delivery of mail or other materials to the resident within 24 hours of delivery by the postal service (including a post office box) and delivery of outgoing mail to the postal service within 24 hours of regularly scheduled postal delivery and pickup service.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A517	(j) Access and Visitation Rights. (1) The resident has the right and the facility must provide immediate access to any resident by the following: (vii) Subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and (viii) Subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.	Interpretive Guidelines §483.10(j)(1)(vii)-(viii) The facility may set reasonable hours for visitation. If it would violate the rights of a roommate to have visitors in the resident's room, the facility must establish alternate areas in the facility for visiting. These areas could include the chapel, a suitable office area, a dining room, or a porch or patio area.
A518	(l) Personal Property. The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.	Interpretive Guidelines §483.10(l) The intent of this regulation is to encourage residents to bring personal possessions into the facility, as space, safety considerations and fire code permits. All residents' possessions must be treated with respect and safeguarded. The facility has the right to limit personal property due to space limitations in the facility or for safety considerations. Survey Procedures and Probes §483.10(l) If residents' rooms have few personal possessions, ask residents and families if-- o They are encouraged to have and to use personal items; o The facility informs them not to bring in certain items and for what reason; and o Their personal property is safe in the facility.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A519	(m) Married couples. The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.	Interpretive Guidelines §483.10(m) The requirement means that when a room is available for a married couple to share, the facility must permit them to share it if they choose.
A522	**§483.12 Admission, Transfer and Discharge Rights.** (a) Transfer and discharge-- (1) Definition: Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.	Interpretive Guidelines §483.12(a)(1) The intent of the regulation on transfer and discharge provisions is to significantly restrict a facility's ability to transfer or discharge a resident once that resident has been admitted to the facility to prevent dumping of high care or difficult residents. This requirement applies to transfer or discharges that are initiated by the facility, not by the resident.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A523	(2) Transfer and discharge requirements. The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless-- (i) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility; (ii) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility; (iii) The safety of individuals in the facility is endangered; (iv) The health of individuals in the facility would otherwise be endangered; (v) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or (vi) The facility ceases to operate.	Interpretive Guidelines §483.12(a)(2) If transfer is due to a significant change in the resident's condition, the facility must conduct the appropriate assessment, prior to any transfer or discharge to determine if a new care plan would allow the facility to meet the resident's needs. If the significant change in the resident's condition is an emergency, immediate transfer should be arranged. Survey Procedures and Probes §483.12(a)(2) During closed record review, determine the reasons for transfer/discharge. o Do records document accurate assessments and attempts through care planning to address the resident's needs through multidisciplinary interventions, accommodation of individual needs, and attention to the resident's customary routine? o Did the resident's physician document the record if the resident was transferred/discharged for the sake of the resident's welfare and the resident's needs could not be met in the facility (e.g., a resident develops an acute condition requiring hospitalization) or the resident's health improved to the extent that the transferred/discharged resident no longer needed the services of the facility? o Did a physician document the record if residents were transferred because the health of individuals in the facility is endangered? o Do the records of residents transferred/discharged due to safety reasons reflect the process by which the facility concluded that in each instance transfer or discharge was necessary? o If the entity to which the resident was discharged is another long term care facility, evaluate the extent to which the discharge summary and the resident's physician justify why the facility could not meet the needs of this resident.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A524	(3) Documentation. When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident's clinical record must be documented. The documentation must be made by-- (i) The resident's physician when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and (ii) A physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section.	Interpretive Guidelines §483.12(a)(3) Documentation of the transfer/discharge may be completed by a physician extender unless prohibited by State law or facility policy.
A525	(4) Notice before transfer. Before a facility transfers or discharges a resident, the facility must-- (i) Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. (ii) Record the reasons in the resident's clinical record; and (iii) Include in the notice the items described in paragraph (a)(6) of this section.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A526	(5) Timing of the Notice. (i) Except when specified in paragraph (a)(5)(ii) of this section, the notice of transfer or discharge required under paragraph (a)(4) of this section must be made by the facility at least 30 days before the resident is transferred or discharged. (ii) Notice may be made as soon as practicable before transfer or discharge when-- (A) The safety of individuals in the facility would be endangered under paragraph (a)(2)(iii) of this section; (B) The health of individuals in the facility would be endangered, under paragraph (a)(2)(iv) of this section; (C) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (a)(2)(ii) of this section; (D) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a)(2)(i) of this section; or (E) A resident has not resided in the facility for 30 days.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A527	(6) Contents of the Notice. The written notice specified in paragraph (a)(4) of this section must include the following: (i) The reason for transfer or discharge; (ii) The effective date of transfer or discharge; (iii) The location to which the resident is transferred or discharged; (iv) A statement that the resident has the right to appeal the action to the State; (v) The name, address and telephone number of the State long term care ombudsman; (vi) For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act; and (vii) For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally Ill Individuals Act.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A528	(7) Orientation for transfer or discharge. A facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.	Interpretive Guidelines §483.12(a)(7) "Sufficient preparation" means the facility informs the resident where he or she is going and assures safe transportation. The facility should actively involve the resident and the resident's family in selecting the new residence. Some examples of orientation may include trial visits by the resident to a new location; working with family; and orienting staff in the receiving facility to the resident's daily patterns. Survey Procedures and Probes §483.12(a)(7) During resident reviews, check social service notes to see if appropriate referrals have been made and, if necessary, if resident counseling has occurred.
A531	**§483.13 Resident behavior and facility practices.** (a) Restraints. The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.	Interpretive Guidelines §483.13(a) The intent of this requirement is for each person to reach his/her highest practicable well-being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints. "Physical restraints" are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily and that restricts freedom of movement or normal access to one's body. "Chemical Restraint" is defined as a psychopharmacologic drug that is used for discipline or convenience and not required to treat medical symptoms. "Discipline" is defined as any action taken by the facility for the purpose of punishing or penalizing residents. "Convenience" is defined as any action taken by the facility to control resident behavior or maintain residents with a lesser amount of effort by the facility and not in the resident's best interest. Medical symptoms that would warrant the use of restraints should be reflected in the comprehensive assessment and care planning. The facility must engage in a systematic and gradual process toward reducing restraints (e.g., gradually increasing the time for ambulation and muscle strengthening activities).

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A531 (Cont)		Survey Procedures an d Probes §483.13(a) Determine if the facility follows a systematic process of evaluation and care planning prior to using restraints. Determine if the interdisciplinary team addressed the risk of decline at the time restraint use was initiated. Did the team institute measures in the care plan to address reversal of any decline in health status? Determine the intended use of any restraints. Was the use for convenience or discipline?
A532	(b) Abuse. The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.	Interpretive Guidelines §483.13(b) The intent of this regulation is to assure that each resident is free from abuse, corporal punishment, and involuntary seclusion. The facility is responsible for preventing abuse, but also for those practices and omissions, neglect and misappropriation of property, that if left unchecked, lead to abuse. Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the individual, family members or legal guardians, friends, or other individuals. "Abuse" is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm or pain or mental anguish, or deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well being. This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish. "Verbal abuse" is defined as any use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. Examples of verbal abuse include, but are not limited to: threats of harm; and saying things to frighten a resident, such as telling a resident that she will never be able to see her family again.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A532 (Cont.)		"Sexual abuse" includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault. "Physical abuse" includes hitting, slapping, pinching and kicking. It also includes controlling behavior through corporal punishment and restraints. "Mental abuse" includes, but is not limited to, humiliation, harassment, threats of punishment or deprivation. "Involuntary seclusion" is defined as separation of a resident from other residents or from his or her room or confinement to his or her room (with or without roommates) against the resident's will, or the will of the resident's legal representative. Emergency or short term monitored separation from other residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident's needs. Survey Procedures and Probes §483.13(b) Offsite, pre-survey review of complaints can focus the survey team's on-site review of actual incidents and predisposing factors to abuse or neglect and misappropriation of property. Report and record any instances where the survey team observes an abusive incident. Completely document who committed the abusive act, the nature of the abuse, and where and when it occurred. Ensure that the facility addresses that incident immediately. If the survey team's observations and resident's responses signal the presence of abuse, determine how the facility prevents and reports abusive behavior. If a resident is being temporarily separated from other residents, for less than 24 hours, as an emergency short-term intervention, answer these questions-- 1. What are the symptoms that led to the consideration of the separation? 2. Are these symptoms caused by failure to-- o Meet individual needs; o Provide meaningful activities; and o Manipulate the resident’s environment?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A532 (Cont.)		3. Can the cause(s) be removed? 4. If the cause(s) cannot be removed, has the facility attempted to use alternatives short of separation? 5. Does the facility use the separation for the least amount of time? 6. To what extent has the resident, surrogate or representative participated in care planning and made an informed choice about separation? 7. Does the facility monitor and adjust care to reduce negative outcomes, while continually trying to find and use less restrictive alternatives? 8. If residents are temporarily separated in secured units, staff should carry keys to these units at all times. 9. If the purpose of the unit is to provide specialized care for residents who are cognitively impaired (through a program of therapeutic activities designed to enable residents to attain and maintain the highest practicable physical, mental or psychosocial well-being) then placement in the unit is not in violation of resident rights, as long as the resident's individual care plan indicates the need for the stated purpose and services provided in the unit and the resident, surrogate, or representative has participated in the placement decision.
A533	(c) Staff treatment of residents. The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property. (1) The facility must— (i) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;	Interpretive Guidelines §483.13(c) The intent of this regulation is to assure that the facility has in place an effective system that prevents mistreatment, neglect and abuse of residents, and misappropriation of resident's property. "Misappropriation of resident's property" is defined as the patterned or deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A534	(ii) Not employ individuals who have been-- (A) Found guilty of abusing, neglecting, or mistreating residents by a court of law; or (B) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and (iii) Report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff to the State nurse aide registry or licensing authorities. (2) The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency). (3) The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress.	Interpretive Guidelines §483.13(c)(1)-(4) The intent of this regulation is to prevent employment of individuals who have been convicted of abusing, neglecting, or mistreating individuals in a health care related setting. In addition to inquiry of the State nurse aide registry or other licensing authorities, the facility should check all staff references and make reasonable efforts to uncover information about any past criminal prosecutions. "Found guilty...by a court of law" applies to situations where the defendant pleads guilty, is found guilty, or pleads nolo contendere. "Finding" is defined as a determination made by the State that validates allegations of abuse, neglect, mistreatment of residents or misappropriation of their property. Any facility staff found guilty of neglect, abuse, or mistreating residents or misappropriation of property by a court of law, must have his or her name entered into the nurse aide registry, or reported to the licensing authority, as appropriate. Survey Procedures and Probes §483.13(c)(1)-(4) During Sample Selection-- 1. If the team has identified a problem in mistreatment, neglect or abuse of residents or misappropriation of their property, then request— o A copy of the facility's policies and procedures regarding abuse prevention: Note particularly the extent to which those policies concern the areas uncovered through complaints and/or previous survey; o Reports of action(s) by a court of law against employees; o Reports of alleged violations involving mistreatment, neglect, abuse, injuries of unknown source, and misappropriation of resident's property; o Reports of the results of these investigations; and o Records of corrective actions taken.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A534 (Cont.)	(4) The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.	2. Spot check employment applications for questions about convictions or mistreatment, neglect or abuse of residents, or misappropriation of their property. Determine if applicants have answered these questions and if affirmative answers had resulted in rejections of employment candidates. 3. Contact the State Nurse Aide Registry or Board of Nursing, as appropriate. Determine if applicants with a finding concerning mistreatment, neglect, abuse of residents or misappropriation of their property have been rejected. 4. Ask for the results of any in-house investigations of mistreatment, neglect, or abuse of residents, misappropriation of their property, or injuries of unknown sources. o Was the administrator notified of the incident and when? o Did investigations begin promptly after the report of the problem? o Is there a record of statements or interviews of the resident, suspect (if one is identified), any eye witnesses and any circumstantial witnesses? o Was relevant documentation reviewed and preserved (e.g., dated dressing which was not changed when treatment recorded change)? o Was the alleged victim examined promptly (if injury was suspected) and the finding documented in the report? o What steps were taken to protect the alleged victim from further abuse (particularly where no suspect has been identified)? o What actions were taken as a result of the investigation? o What corrective action was taken, including informing the nurse aide registry, State licensure authorities, and other agencies (e.g., long-term care ombudsman; adult protective services; Medicaid fraud and abuse unit)?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A537	**§483.15 Quality of Life.** A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life. (f) Activities. (1) The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident. (2) The activities program must be directed by a qualified professional who-- (i) Is a qualified therapeutic recreation specialist or an activities professional who-- (A) Is licensed or registered, if applicable, by the State in which practicing; and (B) Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or (ii) Has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or (iii) Is a qualified occupational therapist or occupational therapy assistant; or	Interpretive Guidelines §483.15(f) A "recognized accrediting body" refers to those organizations or associations recognized as such by certified therapeutic recreation specialists or certified activity professionals or registered occupational therapists. The activities program should be multi-faceted and reflect each individual resident's needs on their care plan. **In a Critical Access Hospital**, the services at §483.15(f) may be directed either by a qualified professional meeting the requirements of §483.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy. Activities can occur at anytime and are not limited to formal activities being provided by activity staff. Others involved may be any facility staff, volunteers, and visitors. Survey Procedures and Probes §483.15(f) Observe individual, group and bedside activities. 1. Are residents who are confined or choose to remain in their rooms provided with suitable in-room activities (e.g., music, reading, visits with individuals who share their interests)? Do any facility staff members assist the resident with activities? 2. If residents sit for long periods of time with no apparently meaningful activities, is the cause-- o The resident's choice; o Failure of any staff or volunteers either to inform residents when activities are occurring or to encourage resident involvement in activities; o Lack of assistance with ambulation; o Lack of sufficient supplies and/or staff to facilitate attendance and participation in the activity programs; or o Program design that fails to reflect the interests or ability levels of residents, such as activities that are too complex?

INTERPRETIVE GUIDELINES - SWING BEDS

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A537 (Cont)	(iv) Has completed a training course approved by the State.	3. For residents selected for review, determine to what extent the activities reflect the individual resident's assessment. 4. Review the activity calendar for the month prior to the survey to determine if the formal activity program: o Reflects the schedules, choices and rights of the residents; o Offers activities at hours convenient to the residents (e.g., morning, afternoon, some evenings and weekends); o Reflects the cultural and religious interests of the resident population; and o Would appeal to both men and women and all age groups living in the facility. 5. Review clinical records and activity attendance records of residents to determine if-- o Activities reflect individual resident history indicated by the comprehensive assessment; o Care plans address activities that are appropriate for each resident based on the comprehensive assessment; o Activities occur as planned; and o Outcomes/responses to activities interventions are identified in the progress notes of each resident. 6. If there are problems with provision of activities, determine if these services are provided by qualified staff.

INTERPRETIVE GUIDELINES - SWING BEDS

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A538	(g) Social Services. (1) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. (2) A facility with more than 120 beds must employ a qualified social worker on a full-time basis. (3) Qualifications of social worker. A qualified social worker is an individual with-- A bachelor's degree in social work or a bachelor's degree in a human services field including but not limited to sociology, special education, rehabilitation counseling, and psychology; and (ii) One year of supervised social work experience in a health care setting working directly with individuals.	Interpretive Guidelines §483.15(g) The intent of this regulation is to assure that all facilities provide for the medically-related social services needs of each resident. This requirement specifies that facilities aggressively identify the need for medically-related social services, and pursue the provision of these services. A qualified social worker need not personally provide all of these services. It is the responsibility of the facility to identify the medically-related social service needs of the resident and assure that the needs are met by the appropriate discipline. "Medically-related social services" means services provided by the facility's staff to assist residents in maintaining or improving their ability to manage their everyday physical, mental, and psychosocial needs. These services could include: o Making arrangements for obtaining needed adaptive equipment, clothing, and personal items; o Maintaining contact with family (with resident's permission) to report on changes in health, current goals, discharge planning, and encouragement to participate in care planning; o Assisting staff to inform residents and those they designate about the resident's health status and health care choices; o Making referrals and obtaining services from outside entities (e.g., talking books, absentee ballots, community wheelchair transportation); o Assisting residents with financial and legal matters (e.g., applying for pensions, referrals to lawyers, referrals to funeral homes for preplanning arrangements); o Discharge planning services (e.g., helping to place a resident on a waiting list for community congregate living, arranging intake for home care services for residents returning home, assisting with transfer arrangements to other facilities); o Providing or arranging provision of needed counseling services; o Assisting residents to determine how they would like to make decisions about their health care, and whether or not they would like anyone else to be involved in those decisions; o Finding options that meet the physical and emotional needs of each resident; o Meeting the needs of residents who are grieving; and o Assisting residents with dental/denture care, podiatric care; eye care; hearing services, and obtaining equipment for mobility or assistive eating devices. Where needed services are not covered by the Medicaid State Plan, facilities are still required to attempt to obtain these services.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A538 (Cont)		Survey Procedures and Probes §483.15(g) For residents selected for review -- o How do facility staff implement social services interventions to assist the resident in meeting treatment goals? o How do staff who are responsible for social work monitor the resident's progress in improving physical, mental and psychosocial functioning? Has goal attainment been evaluated and the care plan changed accordingly? o How does the care plan link goals to psychosocial functioning/well being? o Has the staff responsible for social work established and maintained relationships with the resident's family or legal representative? o What attempts does the facility make to access services for Medicaid recipients when those services are not covered by a Medicaid State Plan? Look for evidence that social services interventions successfully address residents' needs and link social supports, physical care, and physical environment with residents' needs and individuality.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A541	**§483.20 Resident Assessment.** The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity. (l) Discharge summary. When the facility anticipates discharge a resident must have a discharge summary that includes: (1) A recapitulation of the resident's stay; (2) A final summary of the resident's status to include items in paragraph (b)(2) of this section, at the time of the discharge that is available for release to authorized persons and agencies, with the consent of the resident or legal representative; and (3) A post-discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.	Interpretive Guidelines §483.20 The intent of this regulation is to provide the facility with ongoing assessment information necessary to develop a care plan, to provide the appropriate care and services for each resident, and to modify the care plan and care/services based on the resident's status. The facility is expected to use resident observation and communication as the primary source of information when completing the assessment. In addition to direct observation and communication with the resident, the facility should use a variety of other sources, including communication with licensed and non-licensed staff members on all shifts and may include discussions with the resident's physician, family members, or outside consultants and review of the resident's record. Items in (b)(2) of this section would include comprehensive assessments of a resident which were done within 14 days of admission; within 14 days of a significant change in the resident's physical or mental condition; or done on an annual review. These assessments need to be in the final discharge summary.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A544	**§483.45 Specialized rehabilitative services.** (a) Provision of services. If specialized rehabilitative services such as, but not limited to, physical therapy, speech-language pathology, occupa-tional therapy, and mental health rehabilitative services for mental illness and mental retardation, are required in the resident's comprehensive plan of care, the facility must-- (1) Provide the required services; or (2) Obtain the required services from an outside resource (in accordance with §483.75(h) of this part) from a provider of specialized rehabilitative services.	Interpretive Guidelines §483.45(a) The intent of this regulation is to assure that residents receive necessary specialized rehabilitative services as determined by the comprehensive assessment and care plan, to prevent avoidable physical and mental deterioration and to assist them in obtaining or maintaining their highest practicable level of functional and psychosocial well being. Specialized rehabilitative services are considered a facility service and are included within the scope of facility services. They must be provided to residents who need them even when the services are not specifically enumerated in the State plan. No fee can be charged a Medicaid recipient for specialized rehabilitative services because they are covered facility services. A facility is not obligated to provide **specialized rehabilitative services** if it does not have residents who require these services. If a resident develops a need for these services after admission, the facility must either provide the services, or, where appropriate, obtain the service from an outside resource. For a resident with mental illness (MI) or mental retardation (MR) to have his or her specialized needs met, the individual must receive all services necessary to assist the individual in maintaining or achieving as much independence and self determination as possible. Specialized services for mental illness or mental regardation refers to those services to be provided by the State which can only be delivered by personnel or programs other than those of the nursing facility (NF) because the overall level of NF services is not as intense as necessary to meet the individuals needs. "Mental health **rehabilitative services** for MI and MR" refers to those services of lesser frequency or intensity to be implemented by all levels of nursing facility staff who come into contact with the resident who is mentally ill or who has mental retardation. These services are necessary regardless of whether or not they require additional services to be provided for or arranged by the State as specialized services. Mental health rehabilitative services for MI and MR may include, but are not limited to-- o Consistent implementation during the resident's daily routine and across settings, of systematic plans which are designed to change inappropriate behaviors; o Drug therapy and monitoring of the effectiveness and side effects of medications which have been prescribed to change inappropriate behavior or to alter manifestations of psychiatric illness; o Provision of a structured environment for those individuals who are determined to need such structure (e.g., structured socialization activities to diminish tendencies toward isolation and withdrawal);

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A544 (Cont.)		o Development, maintenance and consistent implementation across settings of those programs designed to teach individuals the daily living skills they need to be more independent and self determining including, but not limited to, grooming, personal hygiene, mobility, nutrition, vocational skills, health, drug therapy, mental health education, money management, and maintenance of the living environment; o Crisis intervention services; o Individual, group, and family psychotherapy; o Development of appropriate personal support networks; and o Formal behavior modification progress. Survey Procedures and Probes §483.45(a) Determine the extent of follow through with the comprehensive care plan. Verify from the chart that the resident is receiving frequency and type of therapy as outlined in the care plan. 1. PHYSICAL THERAPY o What did the facility do to improve the resident's muscle strength? The resident's balance? o What did the facility do to determine if an assistive device would enable the resident to reach or maintain his/her highest practicable level of physical function? o If the resident has an assistive device, is he/she encouraged to use it on a regular basis? o What did the facility do to increase the amount of physical activity the resident could do (for example, the number of repetitions of an exercise, the distance walked)? o What did the facility do to prevent or minimize contractures, which could lead to decreased mobility and increased risk of pressure ulcer occurrence?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A544 (Cont.)		2. OCCUPATIONAL THERAPY o What did the facility do to decrease the amount of assistance needed to perform a task? o What did the facility do to decrease behavioral symptoms? o What did the facility do to improve gross and fine motor coordination? o What did the facility do to improve sensory awareness, visual-spatial awareness, and body integration? o What did the facility do to improve memory, problem solving, attention span, and the ability to recognize safety hazards? 3. SPEECH, LANGUAGE PATHOLOGY o What did the facility do to improve auditory comprehension? o What did the facility do to improve speech production? o What did the facility do to improve expressive behavior? o What did the facility do to improve the functional abilities of residents with moderate to severe hearing loss who have received an audiologic evaluation? o For the resident who cannot speak, did the facility assess for a communication board or an alternate means of communication? 4. REHABILITATIVE SERVICES FOR MI AND MR o What did the facility do to decrease incidents of inappropriate behaviors, for individuals with MR, or behavioral symptoms for persons with MI? To increase appropriate behavior? o What did the facility do to identify and treat the underlying factors behind tendencies toward isolation and withdrawal? o What did the facility do to develop and maintain necessary daily living skills?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A544 (Cont.)		o How has the facility modified the training strategies it uses with its residents to account for the special learning needs of its residents with MI or MR? o Questions to ask individuals with MI or MR-- --Who do you talk to when you have a problem or need something? --What do you do when you feel happy? Sad? Can't sleep at night? --In what activities are you involved, and how often?
A545	(b) Qualifications. Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.	Interpretive Guidelines §483.45(b) Specialized rehabilitative services are provided for individual's under a physician's order by a qualified professional. Once the assessment for specialized rehabilitative services is completed, a care plan must be developed, followed, and monitored by a licensed professional. Once a resident has met his or her care plan goals, a licensed professional can either discontinue treatment or initiate a maintenance program which either nursing or restorative aides will follow to maintain functional and physical status. "Qualified personnel" means that professional staff are licensed, certified or registered to provide specialized therapy/rehabilitative services in accordance with applicable State laws. Health rehabilitative services for MI and MR must be implemented consistently by all staff unless the nature of the services is such that they are designated or required to be implemented only be licensed or credentialed personnel. Survey Procedures and Probes §483.45(b) o Determine if there are any problems in quality of care related to maintaining or improving functional abilities. Determine if these problems are attributable in part to the qualifications of specialized rehabilitative services staff. o Determine from the care plan and record that rehabilitative services are provided under the written order of a physician and by qualified personnel. If a problem in a resident's rehabilitative care is identified that is related to the qualifications of the care providers, it may be necessary to validate the care provider's qualifications. If the facility does not employ professional staff who have experience working directly with or designing training or treatment programs to meet the needs of individuals with MI or MR, how has the facility arranged for the necessary direct or staff training services to be provided?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A548	**§483.55 Dental services**. The facility must assist residents in obtaining routine and 24 hour emergency dental care.	Interpretive Guidelines §483.55 This requirement makes the facility directly responsible for the dental care needs of its residents. The facility must ensure that a dentist is available for residents. They can satisfy this requirement by employing a staff dentist or having a contract/arrangement with a dentist to provide services. For Medicare and private pay residents, facilities are responsible for having the services available, but they may impose an additional charge for the services. Medicaid residents may not be charged. For all residents of the facility, if they are unable to pay for needed dental services, the facility should attempt to find alternative funding sources or alternative service delivery systems so that the resident is able to maintain his/her highest practicable level of well being.
A549	(a) Skilled nursing facilities. A facility (1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, routine and emergency dental services to meet the needs of each resident; (2) May charge a Medicare resident an additional amount for routine and emergency dental services;	Interpretive Guidelines §483.55(a) "Routine dental services" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures). "Emergency dental services" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity, appropriately treated by a dentist that requires immediate attention. "Prompt referral' means, within reason, as soon as the dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A550	(3) Must if necessary, assist the resident-- (i) In making appointments; and (ii) By arranging for transportation to and from the dentist's office; and (4) Promptly refer residents with lost or damaged dentures to a dentist.	Survey Procedures and Probes §483.55(a) Do residents selected for comprehensive or focused reviews, as appropriate, with dentures, use them? Are residents missing teeth and may be in need of dentures? Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene? Are resident's dentures intact? Properly fitted? Interpretive Guidelines §483.55(b) NOTE: §483.55(b) Nursing Facilities does not usually apply to Medicare reimbursed swing-bed residents because Medicare swing-bed residents receive skilled nursing care comparable to services provided in a SNF not a NF. If a swing-bed resident is a NF level patient, apply standard §483.55(b) as appropriate.
A551	(b) Nursing facilities. The facility (1) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, the following dental services to meet the needs of each resident: (i) Routine dental service (to the extent covered under the State plan); and (ii)Emergency dental services;	Interpretive Guidelines §483.55(b) "Routine dental services" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures). "Emergency dental services" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity, appropriately treated by a dentist that requires immediate attention. "Prompt referral' means, within reason, as soon as the dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A552	(2) Must, if necessary, assist the resident (i) In making appointments; and (ii) By arranging for transportation to and from the dentist's office; and (3) Must promptly refer residents with lost or damaged dentures to a dentist.	Survey Procedures and Probes §483.55(b) Do residents selected for comprehensive or focused reviews, as appropriate, with dentures, use them? Are residents missing teeth and may be in need of dentures? Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene? Are resident's dentures intact? Properly fitted?

APPENDIX U

SURVEY PROCEDURES AND INTERPRETIVE GUIDELINES FOR RESPONSIBILITIES OF MEDICARE PARTICIPATING RELIGIOUS NONMEDICAL HEALTHCARE INSTITUTIONS

Survey Procedures and Interpretive Guidelines for Responsibilities of Religious Nonmedical Healthcare Institutions

PART 1

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II. Survey/Resurvey

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- Task 2 - Entrance Conference
- Task 3 - Tour of Facility
- Task 4 - Information Gathering

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  E - Food Services
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PART 2

Column I. Tag Number

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SURVEY PROCEDURES FOR RESPONSIBILITIES OF MEDICARE PARTICIPATING RELIGIOUS NONMEDICAL HEALTHCARE INSTITUTIONS

I. GENERAL INFORMATION

Section 4454 of the Balanced Budget Act of 1997 (BBA'97, Public Law No. 105-33, enacted August 5, 1997) deletes statutory references to Christian Science Sanatoria and amended the following sections of the Social Security Act (the Act): §§1821, 1861(e), (y) and (ss), 1869, and 1878 (Medicare provisions); 1902(a) and 1908(e)(1) (Medicaid provisions); and 1122 (h) and 1162 (conforming provisions). Additionally, §4454 provides for coverage of inpatient services furnished in qualified religious nonmedical health care institutions (RNHCIs) under Medicare and as a State Plan option under Medicaid. The new amendments make it possible for RNHCIs meeting the defining criteria in §4454 of BBA'97 or §1861(ss)(1), to participate in the Medicare and/or Medicaid program. The RNHCI provider is responsible for meeting both Conditions of Coverage and Conditions of Participation to qualify as a Medicare provider and that portion of the Conditions of Coverage that define an RNHCI and the Conditions of Participation to qualify as a Medicaid provider.

The Boston Regional Office has the primary responsibility for the approval and certification process to ensure and verify that the RNHCI conforms to specific Conditions of Coverage and all of the Conditions of Participation. An RNHCI is a provider that meets the definition as described in §1861(ss)(1) of the Act and meets the following qualifying Medicare Conditions of Coverage provisions (§403.720). To qualify as a Medicare or Medicaid RNHCI an institution must meet all ten of the following requirements:

- Is described in subsection (c)(3) of §501 of the Internal Revenue Code of 1986 and is exempt from taxes under subsection 501(a);

- Is lawfully operated under all applicable Federal, State, and local laws and regulations;

- Furnishes only nonmedical nursing items and services to beneficiaries who choose to rely solely upon a religious method of healing, and for whom the acceptance of medical services would be inconsistent with their religious beliefs. (NOTE: Religious components of the healing are not covered);

- Furnishes nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of nonmedical patients. For example, caring for the physical needs such as assistance with activities of daily living; assistance in moving, positioning, and ambulation; nutritional needs; and comfort and support measures;

- Furnishes nonmedical items and services to inpatients on a 24-hour basis;

- Does not furnish, on the basis of religious beliefs, through its personnel or otherwise, medical items and services (including any medical

screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients;

- Is not owned by, under common ownership with, or has an ownership interest of 5 percent or more in, a provider of medical treatment or services and is not affiliated with a provider of medical treatment or services or with an individual who has an ownership interest of 5 percent or more in a provider of medical treatment or services (permissible affiliations are described in §403.738(C));

- Has in effect a utilization review plan that meets the requirements of §403.720(a)(8);

o Provides information HCFA may require to implement §1821 of the Act, including information relating to quality of care and coverage determinations; and

o Meets other requirements HCFA finds necessary in the interest of the health and safety of the patients who receive services in the institution.

A. Other Medicare Conditions of Coverage.--The remaining Conditions of Coverage are specific to Medicare; however, a State may elect to employ any or of all these requirements within their optional Medicaid State plan amendment.

B. Valid Election Requirements.--The regulations at §403.724, present the elements necessary for a Medicare beneficiary to complete an election to receive care in an RNHCI. The RO determines whether or not the RNHCI has adequately ensured that the Medicare beneficiary's valid election statement has been included with the RNHCI's administrative records and/or patient care records.

NOTE: The facility is to provide the fiscal intermediary the original of the election statement which will be used for each Medicare beneficiary in the RNHCI and retain a copy in its files.

The provisions for valid elections include the following general requirements:

o The election statement must be made by the Medicare beneficiary or by his or her legal
representative. It must include written statements that:

- The beneficiary is conscientiously opposed to acceptance of nonexcepted medical treatment;

- The beneficiary acknowledges that acceptance is inconsistent with his or her sincere religious beliefs;

- The beneficiary acknowledges that receipt of nonexcepted medical care constitutes a revocation of the election and may limit further receipt of services in an RNHCI;

- The beneficiary acknowledges that the election may be revoked by submitting a written statement to HCFA; and

- The beneficiary acknowledges that the revocation will not prevent or delay access to medical services available under Medicare Part A in other types of facilities.

A valid election must also:

- Be signed and dated by the beneficiary or by his or her legal representative, not prior to reaching Medicare eligibility and beneficiary status;

- Be notarized;

- Include an original copy submitted on file to HCFA (HCFA is represented for this purpose by the intermediary); and

- Include any other information obtained regarding prior elections or revocations.

A beneficiary's election is revoked by one of the following:

- The beneficiary receives nonexcepted medical treatment for which Medicare payment is made; or
- The beneficiary voluntarily revokes the election and notifies HCFA in writing.

NOTE: "Excepted" and "nonexcepted" medical care are defined in §403.702. The receipt of excepted medical care or treatment as defined in §403.702 does not revoke the election made by a beneficiary.

The beneficiary's ability to elect is limited once the election has been made and revoked twice (see §403.724(C)).

II. SURVEY/RESURVEY

TASK 1 - PRESURVEY PREPARATION

The RO reviews various documents of record and various sources of information available about the facility. Presurvey preparation is useful in identifying questions and concerns related to the Conditions of Coverage, Conditions of Participation, and in determining composition of the survey team and the time required to perform a survey/resurvey.

Presurvey preparation includes reviewing such information as:

- Current IRS religious not-for-profit status;
- Provider information on file, including agreement with HCFA, as an extended care hospital;
- Applicable State and local laws, particularly as they relate to licensure and monitoring of operations;
- Previous OSCAR survey data;
- Form HCFA-855 and Form HCFA-1513 (for Medicaid only facilities);
- Other elements of the Conditions of Coverage, to be sure the provider is meeting the definition of an RNHCI before starting the onsite visit;
- Licensure records;
- Fire inspection reports;

- Complaints; and
- Previous survey reports including Life Safety Code (LSC).

TASK 2 - ENTRANCE CONFERENCE

Upon entering the facility, the surveyor introduces him/herself to the authorized representative (governing body, administrator) to outline the survey plan and to talk with other staff/personnel to obtain information. Indicate that the surveyor(s) will be looking at both Conditions of Coverage and Conditions of Participation.

The authorized representative is considered as the key contact person in the facility. The surveyor interviews the authorized representative first. There are elements related to each condition that the surveyor may need to discuss with the authorized representative. He/she will be able to direct the surveyor to other staff to interview relative to specific standards and other requirements. However, contacts are not limited solely to the authorized representative. Even if the authorized representative feels that he/she can answer most of the questions, the facts must be verified through record reviews, other source documents and interviews. The RO investigation must be complete enough to document whether the HCFA requirements are met and the provider is in compliance with the related condition(s).

Inform the authorized representative that there will be interviews with staff, patients, family members, friends, and legal representative. Convey that these interviews are conducted privately, unless the interviewee requests the presence of another person. Ask the authorized representative to ensure that there are times during the survey when patients can contact the surveyor without facility staff being present. Have the facility provide the following items immediately:

- The facility's roster showing patients' names, gender, age, length of stay, utilization review plan, discharge, and/or transfer with destinations of each patient. Also indicate patients who communicate with non-oral communication devices, sign language, or who speak a language other than the dominant language of the facility;

- Names of key facility personnel, their title(s), and a description of their responsibilities associated with patient care/services, such as administrator, director, nursing staff, volunteers, food service supervisor, plant engineer, housekeeping supervisor, governing body personnel, and persons responsible for quality assessment;

- A copy of the written information on file that is provided to patients regarding their rights and election statements;

- A description of and the hours of operation for food services and housekeeping;

- A copy of the facility admission contract(s) for all patients regarding

Medicare, Medicaid, and other payment sources;

- Identification of any transfer or discharge that is planned (not yet completed);

- Records or reports of abuse/accident/incident;

- A copy of the actual working schedules for all staff for the days of survey;

- A description/copy of meals times, dining location, copies of all menus; and

- Any new information or changes that have occurred from the preparation time to the actual time of the survey occurrence.

During the introductory meeting with the authorized representative, the surveyor alerts him/her that if the facility is planning to record the exit conference, a copy of the tape must be made available to the surveyor(s) at the conclusion of the conference. A surveyor(s) should not accept a promise that a copy of the tape will be mailed at a later date.

TASK 3 - TOUR OF THE FACILITY

The authorized representative informs staff that the surveyor will be communicating with them throughout the survey and will ask for facility assistance when needed. Staff are advised that they have the opportunity to provide surveyors with any information that would clarify any issue. The authorized representative or staff/personnel should take the surveyor(s) on a tour of the facility. This will allow facility staff sufficient time to gather the information requested during the Entrance Conference. The purpose of the facility tour is two-fold. First, it gives the surveyor(s) their first understanding of the layout of the facility and the location of different areas which will be investigated during the survey. Second, it is a good opportunity to make notes concerning the environment or atmosphere of the facility as a whole and how the patients and staff function within it.

TASK 4 -INFORMATION GATHERING

Information gathering techniques include observation, interviews, and record review as critical components of making decisions as to whether the RNHCI has met requirements. The objective is to provide the surveyor with enough information about the facility, patients, staff, and environmental conditions to make compliance decisions. These techniques are interrelated and may often be performed concurrently.

A. Section 403.720(a), Conditions for Coverage (Medicare and Medicaid).--Building on information obtained by review of documents and interview with staff/personnel, determine if all ten critical conditions in this section are met in order for the facility to meet the RNHCI definition.

B. Section 403.720(b), Conditions for Coverage (Medicare only).--Surveyors

review election documents for: all of the elements required; beneficiary's or his/her legal representative's signature, valid notarization; and dated on or before the date of admission to the RNHCI (see §403.724).

C. Section 403.730, Patient Rights.--Surveyors conduct interview of patients, family members, or visitors in order to assess his/her understanding and staffs' knowledge of and involvement in:

- Patients' rights process of being informed before furnishing care to the patients, election process, prompt resolution of grievance process;

- Participation in the development and implementation of the plan of care in a safe setting;

- Formulation of advance directives;

- Freedom from verbal, psychological and physical abuse and misappropriation of property; and freedom from the use of restraints; and

- Confidentiality of records and disclosure.

The interviews provide information about the relationship between staff and patients that will assist you in deciding what additional observations and record information are necessary.

Surveyors must observe the facility environment to determine the relationship between the patient needs and preferences, determine what staff do with and for the patient throughout the day or evening, and to assess whether the physical features of the environment endangers a patient's, visitor's, or staff's safety and well-being.

Review patient's records to ensure proper documentation of patient rights. Review facility policies and procedures regarding how the facility is addressing complaints, misappropriation of property, and confidentiality of records. Conduct a detailed review of individual patient's records for what you need, not the whole record.

D. Section 403.732, Quality Assessment and Performance Improvement.--Surveyors are to conduct interviews of staff to assess staffs' knowledge, understanding and involvement in the facility's quality assessment program and the extent to which it measures, analyzes, tracks and improves, performance. Surveyors must keep focused on the fact that the RNHCI is a nonmedical model and will not use diagnosis, laboratory findings, medical/surgical procedures or therapies as part of quality assessment and performance improvement.

Surveyors are to observe staff as they address identified priorities put in place by the governing body in all program departments, functions and contracted services performed.

Surveyors must review facility policies, procedures, staff training programs, and where adverse outcome is identified and indications of action taken.

E. Section 403.734, Food Services.--Surveyors must interview patients, religious nonmedical nursing staff, kitchen staff, and housekeeping staff on aspects of food services.

Surveyors observe the facility's food storage, preparation, and distribution of

food served. Appearance of kitchen staff and kitchen environment is important. Note whether food substitutes are available.

Surveyors review policy and procedures for kitchen and housekeeping procedures.

F. Section 403.740, Staffing.--Surveyor observations are important in determining what relationship exists between the staff and patient. As a result of any observation, the surveyor should be able to determine:

- Whether the RNHCI attempts to find out what patients need;

- How needs are assessed, care is delivered and if care modifications are incorporated as appropriate; and

- Whether effective interaction occurs between staff and patients.

Determine from observations of RNHCI staff if staff communicates with each patient in a manner understandable to that patient, and others. In the absence of finding appropriate interaction between staff and patients during observations, it may be necessary to determine whether or not staff members are knowledgeable about patient care needs and services. If possible, interview the particular staff member following the interval in which the patient was observed. Interviews are intended to:

- Provide staff the opportunity to give what they believe is pertinent information, and to determine how the patient perceives the services delivered by the RNHCI; and

- Collect and clarify information gathered during observations.

RNHCI personnel should collectively provide care services that maintain or improve the patient's quality of care and are as error-free as possible. Staff members will bring different knowledge and experience to the patient care services team.

Based on staff interviews, determine the extent family, guardians or advocates are involved with the patient. Some of these individuals may be selected for more in-depth interview. Include staff or patients who use alternate means of communication, such as sign language. Interviews of staff members will include persons involved with direct and indirect patient services (e.g. admission, discharge planning, religious nonmedical nursing personnel, food services, etc.). If the person responsible for a specific service is not available, a designee may be interviewed. Early in the survey process identify which individuals may be interviewed. Interview staff about training and supervision along with administrative areas. Find out about roles and responsibilities.

Interview questions are open ended to allow for more complete responses that will assist the surveyor in determining whether the RNHCI has staff that are qualified and experienced to meet patients needs (see §493.740).

The record review is intended to:

- Obtain information to direct initial and/or additional observations and interviews;

- Provide the surveyor a picture of the current status of the RNHCI's operations and care services provided to patients; and

- Assist the surveyor in evaluating assessments and care plans.

Review the personnel records. Record review will include a review of work experience, as well as staff health and training.

The religious aspects of care are the financial responsibility of the patient.

NOTE: Use the record review to obtain information necessary to validate and/or clarify (existing and modified) information obtained through offsite pre-survey and/or onsite observation and interviews.

G. Section 403.742, Physical Environment.--The objective is to view all patient, staff and public areas of the facility to ensure a safe physical plant and overall environment. The RNHCI facility must be toured as a whole, even areas not specifically for patient use. This is to ensure that there are adequate and properly maintained emergency systems, fire detection alarm and extinguishing systems. Procedures should be in place for proper storage, disposal of trash, proper ventilation, lights, and temperature controls. In addition, a written disaster plan to address loss of power, water, sewer, facilities emergency gas and water supply, and effective pest control should be evident.

H. Section 403.744, Life Safety Code.--The objective is to use collective onsite observations and interviews with RNHCI staff/patients as a mechanism to report any questionable information that should be noted and referred to the Life Safety Code inspector. Surveyors should keep routine Life Safety Code requirements in mind when conducting their investigation of the physical environment of the facility.

I. Section 403.746,Utilization Review (UR).--The objective is to determine from surveyor observation, interview, and record review that the RNHCI has a utilization review plan (and other documentation) to determine the needs and appropriateness of those services furnished by the RNHCI staff to patients.

Record review establishes whether the RNHCI has in effect a utilization review plan that is:

- Responsible and has the approval of the governing body;
- Conducted by a committee that maintains a system of records on deliberations and decisions;
- Reviewing the necessity of inpatient admission and continued stay for all patients who are eligible for benefits under Medicare Part A or Medicaid;
- Providing written notification of a recommendation to all involved parties on a timely basis, and
- Administered by a committee which is composed of at least the following members: (a) the governing body, (b) administrator or other individual responsible for the oversight of the RNHCI, (c) the supervisor of religious non-medical nursing staff, and (d) other staff as appropriate.

Review the minutes of the UR committee to verify that they include:

- Dates of meetings and names of members in attendance;
- Efficient use of available resources;

- Number of extended stay reviews approved since the last meeting with reasons for all recommendations for or against; and
- Status report on any action taken.

TASK 5 - ARRIVING AT A DETERMINATION

A deficiency determination is made when the facility has failed to meet one or more of the condition level requirements.

A facility's compliance with the Conditions of Coverage (including election requirements), and the Conditions of Participation is a decision that is based on the objective input of each member of the team, including specialty surveyors. If the survey was performed by a team, then all team members should meet to discuss the findings and collaboratively reach a positive or negative determination.

TASK 6 - EXIT CONFERENCE

A. Purpose of Exit Conference.--The purpose of the exit conference is to inform the RNHCI staff of the survey team's observations and preliminary findings. It is not to provide the facility with a full accounting of the deficiencies that will be cited. These will be determined upon review of the team's observations and findings during the survey write-up. This should be made clear to the facility.

The exit conference also provides an opportunity for the RNHCI to present additional information it believes is pertinent to the preliminary identified findings. Because of the ongoing dialogue between surveyors and facility staff during the survey, there should be few instances where the RNHCI is not aware of surveyor concerns or has not had an opportunity to present additional information prior to the exit conference.

B. Conducting the Exit Conference.--Conduct the Exit Conference with the RNHCI personnel and other invited staff/individuals. The team may provide an abbreviated exit conference specifically for patients after completion of the RNHCI's exit conference. Do not discuss survey results in a manner that reveals the identity of an individual staff member or patient. Provide information in a manner that is understandable to those present.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R93	**§ 403.720 Conditions for coverage.** Medicare covers services furnished in an RNHCI if the following conditions are met:	
R94	(a) The provider meets the definition of an RNHCI as defined in section 1861(ss)(1) of the Act. That is, it is an institution that: (1) Is described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxes under section 501(a). (2) Is lawfully operated under all applicable Federal, State, and local laws and regulations. (3) Furnishes only nonmedical nursing items and services to beneficiaries who choose to rely solely upon a religious method of healing and for whom the acceptance of medical services would be inconsistent with their religious beliefs. (4) Furnishes nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of nonmedical patients. (5) Furnishes nonmedical items and services to inpatients on a 24-hour basis. (6) Does not furnish, on the basis of religious beliefs, through its personnel or otherwise medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients. (7) Is not owned by, is not under common ownership with, or does not have an ownership interest of 5 percent or more in, a provider of medical treatment or services and	Guideline: §403.720(a) The provider must meet all 10 of the regulatory requirements in order to meet the definition of an RNHCI. Procedure: §403.720(a)(1) Verify with IRS current 501(c)(3) status of the RNHCI, which may have changed since initial application. Procedure: §403.720(a)(2) Since these are nonmedical facilities there is a wide range in how States view or consider these facilities. Prior to going onsite find out if the given State licenses or monitors the facilities. Guideline: §403.720(a)(3) Only nonmedical nursing services are provided to beneficiaries. The religious services provided to the beneficiary are not to be considered as part of religious nonmedical nursing services. Guideline: §403.720(a)(4) Alternative medicine is considered medical care in reviewing the care or services provided to these beneficiaries. Procedure: §403.720(a)(5) Verify that services are provided on a 24-hour basis. Guideline: §403.720(a)(6) Immunizations may only be administered if required by law and a health care practitioner comes to the facility for the mandated administration of the vaccine. Procedure: §403.720(a)(7) Verify ownership using Form HCFA-855 and/or Form HCFA-1513 as applicable.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R94 (Cont.)	is not affiliated with a provider of medical treatment or services or with an individual who has an ownership interest of 5 percent or more in, a provider of medical treatment or services. (Permissible affiliations are described at § 403.738(c).) (8) Has in effect a utilization review plan that sets forth the following: (i) Provides for review of the admissions to the institution, the duration of stays, and the need for continuous extended duration of stays in the institution, and the items and services furnished by the institution. (ii) Requires that reviews be made by an appropriate committee of the institution that included the individuals responsible for overall administration and for supervision of nursing personnel at the institution. (iii) Provides that records be maintained of the meetings, decisions, and actions of the review committee. (iv) Meets other requirements as the Secretary finds necessary to establish an effective utilization review plan. (9) Provides information HCFA may require to implement section 1821 of the Act, including information relating to quality of care and coverage decisions. (10) Meets other requirements HCFA finds necessary in the interest of the health and safety of the patients who receive services in the institution. These requirements are the conditions of participation in this subpart.	Procedure: §403.720(a)(9) Review the facility system of records to assure that they support coverage decisions and quality of care issues. Review all files for beneficiary elections for religious nonmedical health care institution services. Guideline: §403.720(a)(10) In addition to the Conditions of Coverage a facility must meet the Conditions of Participation and be surveyed accordingly.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R95	(b) The provider meets the conditions of participation cited in §§ 403.730 through 403.746. (A provider may be deemed to meet conditions of participation in accordance with part 488 of this chapter.)	
R96	(c) The provider has a valid provider agreement as a hospital with HCFA in accordance with part 489 of this chapter and for payment purposes is classified as an extended care hospital.	
R97	(d) The beneficiary has a condition that would make him or her eligible to receive services covered under Medicare Part A as an inpatient in a hospital or SNF.	Procedure: §403.720(d) Review the utilization review committee notes and nurses' notes.
R98	(e) The beneficiary has a valid election as described in § 403.724 in effect for Medicare covered services furnished in an RNHCI.	
R99	**§403.724 Valid election requirements.** (a) General requirements. An election statement must be made by the Medicare beneficiary or his or her legal representative. (1) The election must be a written statement that must include the following statements: (i) The beneficiary is conscientiously opposed to acceptance of nonexcepted medical treatment. (ii) The beneficiary acknowledges that the acceptance of nonexcepted medical treatment is inconsistent with his or her sincere religious beliefs. (iii) The beneficiary acknowledges that the receipt of nonexcepted medical treatment constitutes a revocation of the election and may limit further receipt of services in an RNHCI.	Guideline: §403.724(a) The Election means a written statement signed by the patient to choose to receive nonmedical care for religious reasons. Excepted medical care means medical care that is received involuntarily or required under Federal, State, or local law. Each RNHCI has the ability to customize the election form used by beneficiaries. However, the prescribed list of content stated in the regulation must be included in order to qualify as a legal election of RNHCI care or services. The six major items in the regulatory column may be used as a check list in reviewing elections.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R99 (Cont.)	(iv) The beneficiary acknowledges that the election may be revoked by submitting a written statement to HCFA. (v) The beneficiary acknowledges that revocation of the election will not prevent or delay access to medical services available under Medicare Part A in facilities other than RNHCIs. (2) The election must be signed and dated by the beneficiary or his or her legal representative. (3) The election must be notarized. (4) The RNHCI must keep a copy of the election statement on file and submit the original to HCFA with any information obtained regarding prior elections or revocations. (5) The election becomes effective on the date it is signed. (6) The election remains in effect until revoked.	
R99 (Cont.)	(b) Revocation of election. (1) A beneficiary's election is revoked by one of the following: (i) The beneficiary receives nonexcepted medical treatment for which Medicare payment is requested. (ii) The beneficiary voluntarily revokes the election and notifies HCFA in writing. (2) The receipt of excepted medical treatment as defined in § 403.702 does not revoke the election made by a beneficiary.	Guideline: §403.724(b) This is included for your information rather than as a survey item.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(c) Limitation on subsequent elections. (1) If a beneficiary's election has been made and revoked twice, the following limitations on subsequent elections apply: (i) The third election is not effective until 1 year after the date of the most recent revocation. (ii) Any succeeding elections are not effective until 5 years after the date of the most recent revocation. (2) HCFA will not accept as the basis for payment of any claim any elections executed on or after January 1 of the calendar year in which the sunset provision described in § 403.756 becomes effective.	Guideline: §403.724(c) This is included for your information rather than as a survey item.
R100	**§ 403.730 Condition of participation Patient Rights.** An RNHCI must protect and promote each patient's rights.	Intent: §403.730: Patient Rights The intent of this Condition of Participation is to ensure that patient rights are protected and that the facility actively promotes the exercising of rights for each patient. This includes anyone who faces barriers (such as communication problems, hearing problems, and cognition limits) in the exercise of these rights. All patients in RNHCIs have rights guaranteed under Federal and State law.
R101	(a) Standard: Notice of Rights. The RNHCI must do the following: (1) Inform each patient of his or her rights in advance of furnishing patient care.	Procedure: §403.730(a)(1) Determine if individuals and representatives are aware of the individual's rights and the rules of the facility. Guideline: §403.730(a)(1) The RNHCI has provided information to the patient and representatives in terms and in a language he or she understands. If the patient's knowledge of English or the predominant language of the facility is inadequate for comprehension, a means to communicate in a language familiar to the patient must be available and implemented. The facility should have written translations, as applicable, of its statements of rights and responsibilities, and should make the services of an interpreter available if needed. For hearing impaired patients who communicate by signing, the facility is expected to provide an interpreter. Large print text of the facility statement of patient rights and responsibilities should also be available. When State or Federal laws regarding patient rights change during a patient stay, the patient and/or his or her legal representative must be promptly informed of these changes.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R101 (Cont.)		Probe: §403.730(a)(1) Does the facility have a formalized statement of rights and responsibilities? Does the facility verify that patients have received and understand their rights and responsibilities?
R102	(2) Have a process for prompt resolution of grievances, including a specific person within the facility whom a patient may contact to file a grievance. In addition, the facility must provide patients with information about the facility's process as well as with contact information for appropriate State and Federal resources.	Intent: §403.730(a)(2) The intent of this regulation is to provide an opportunity for patients to express in a means or communicate in a familiar language grievances, and for the facility to resolve any grievances. It is expected that facilities will have a grievance process that allows patients to express concerns without retribution, and resolves grievances to the extent possible. The facility should maintain a system of receipt and resolution of grievances (such as a log) as well as provide patients with names, addresses, and telephone numbers of appropriate State and Federal resources.
R103	(b) Standard: Exercise of Rights. The patient has the right to: (1) Be informed of his or her rights and to participate in the development and implementation of his or her plan of care.	Procedure: §403.730(b)(1) Discuss with the patient, the services that he or she is receiving specific to the plan of care. Ask the patient how he or she was told of any changes in the plan of care. Discuss the changes and see if the patient has received written information and if the patient understands the information. Determine the extent to which the facility initiates activities that involve the patient in his or her care. If the patient refused to participate, interview the patient to verify his/her refusal. Probe: §403.730(b)(1) What do you observe about the interaction between staff and patients? Is there evidence that the patient was included or proactively involved in his/her plan of care?
R104	(2) Make decisions regarding his or her care, including transfer and discharge from the RNHCI. (See § 403.736 for discharge and transfer requirements.)	Probe: §403.730(b)(2) Is there evidence that each patient was given information regarding the right to make decisions?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R105	(3) Formulate advance directives and expect staff who furnish care in the RNHCI to comply with those directives, in accordance with part 489, Subpart I of this chapter. For purposes of conforming with the requirement in § 489.102 that there be documentation in the patient's medical records concerning advance directives, the patient care records of a beneficiary in an RNHCI are equivalent to medical records held by other providers.	Guideline: §403.730(b)(3) Advance directives are particularly important for a patient choosing to rely solely upon religious nonmedical methods of healing, as it makes his or her wishes known in the event he or she becomes incapacitated and unable to make health care choices. An advance directive could lead to the provision of nonexcepted medical care, and thus effectively revoke an Election, or support the choice made in that Election, and must be honored by the facility. Procedure: §403.730(b)(3) Ensure that an Election form that complies with §403.724(a) is on file for each patient. Revocations of elections must also be on file. Ensure that there is evidence that the patient has had the opportunity to formulate his or her advance directive. Corroborate through patient interviews.
R106	(c) Standard: Privacy and safety. The patient has the right to the following: (1) Personal privacy.	Guidelines: §403.730(c)(1-2) Personal privacy includes accommodations, written and telephone communications, personal care, visits, and meetings of family and patient groups, but this does not require the facility to provide a private room for each patient. Facility staff must examine and care for patients in a manner that maintains the privacy of patients' bodies. A patient must be granted privacy when toileting and in other activities of personal hygiene. If a patient requires assistance, authorized staff should respect the patient's need for privacy. People not involved in the care of the patient should not be present during care, nor should video or other electronic monitoring/recording methods be used without the patient's consent. Prior to the provision of personal care and services, staff should remove the patient from public view to prevent unnecessary exposure of the patient's body parts (using means such as privacy curtains, closed patient room doors, clothing and/or draping). The intention of this requirement is to specify that each patient receives care in an environment that is considered to be reasonably safe. For example, RNHCI staff should follow current standards of practice for patient environmental safety, infection control, and security. Other safe setting includes but is not limited to properly maintained assistive devices (wheelchair, walker, cane, hearing aide), bathing facilities with non-slip surfaces, electrical appliances without frayed wires or exposed heating elements, proper radiator temperatures, proper water temperatures in hand sinks, and bathing facilities which cannot scald or harm patients. Probe: §403.730(c)(2) What are the RNHCI's policies and procedures for patient environmental safety, infection control, and security? Does the facility notify appropriate agencies of public health concern as required?
R107	(2) Care in a safe setting.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R108	(3) Freedom from verbal, psychological, and physical abuse, and misappropriation of property.	Guideline: §403.730(c)(3) Patients must not be subjected to any type of abuse by any individual, including but not limited to staff, other patients, consultants, volunteers, family members, legal guardians, friends or other individuals. "Abuse" means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish (see 42 CFR §488.301). This includes staff neglect or indifference to infliction of injury or intimidation of one patient by another. Neglect means a failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. (See 42 CFR §488.301) Surveyor should keep in mind that this is non-medical model and should not expect to see medical care given. Patient should receive the care indicated in their care plan. This also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. This presumes that instances of abuse of all patients, even those in a coma, cause physical harm, or pain or mental anguish. "Misappropriation of property" means the deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a patient's belongings or money without the patient's consent. (See 42 CFR § 488.301) The facility must have a mechanism in place that is designed to identify potential abuse situations, investigate allegations, and protect patients and staff during investigations. Through the quality assessment and performance improvement system and staff training, the facility must demonstrate ongoing attempts to prevent future incidents of abuse. Procedure: §403.730(c)(3) If during the course of a survey, surveyors identify potential abuse situations, investigate allegations through interviews, observations, and record reviews. Report and record any instances where the survey team observes an abusive incident. Completely document who committed the alleged abusive act, nature of the abuse, and where and when it occurred. Ensure that the facility addresses the incident immediately. Probes: §403.730(c)(3) What type of complaints do individuals report (if any) and how well does the facility respond? Are adequate systems in place to protect patients from abuse and misappropriation of property? Are incidents reported appropriately?

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R109	(4) Freedom from the use of restraints.	Guidelines: §403.730(c)(4) and (5) Restraint and seclusion use may constitute an accident hazard. Professional standards of practice have eliminated the need for physical restraints except under limited medical circumstances. **RNHCIs may not use restraints**. The facility may not use restraints in violation of the regulation solely because a surrogate or representative has approved or requested them. Restraints means any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body. Restraints include, but are not limited to, leg restraints, arm restraints, hand mitts, soft ties or vests, lap cushions and lap trays the patient cannot remove. Also included as restraints are facility practices such as: o Using bed rails to keep a patient from voluntarily getting out of bed as opposed to enhancing mobility while in bed; o Tucking in a sheet so tightly that a bed bound patient cannot move; o Using wheelchair safety bars to prevent a patient from rising from the chair; o Placing a patient in a chair that prevents rising; and o Placing a patient who uses a wheelchair so close to a wall that the wall prevents the patient from rising.
R110	(5) Freedom from involuntary seclusion. (d) Standard: Confidentiality of patient records. For any patient care records or election information it maintains on patients, the RNHCI must establish procedures to do the following:	Guideline: §403.730(c)(5) Involuntary seclusion is the involuntary confinement of a person alone in a room or an area where the person is physically prevented from leaving. A patient who is involuntarily in a room isolated from the rest of a unit should be considered in seclusion. **RNHCIs may not use seclusion**. Guidelines: §403.730(d)(1-4) The patient has the right to have his or her care records maintained in a confidential manner.

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R111	(1) Safeguard the privacy of any information that identifies a particular patient. Information from, or copies of, records may be released only to authorized individuals, and the RNHCI must ensure that unauthorized individuals cannot gain access to or alter patient records. Original patient care records must be released only in accordance with Federal or State laws, court orders, or subpoenas.	Probes: §403.730(d)(1-4) How does the facility ensure the confidentiality of patient records? Does the facility instruct the caretaker and authorized individual about protecting the confidentiality of the record, if the facility leaves a portion of the record with the caretaker and/or authorized individual? What evidence indicates that each patient is informed of policies and procedures concerning his/her record disclosure?
R112	(2) Maintain the records and information in an accurate and timely manner	
R113	(3) Ensure timely access by patients to the records and other information that pertains to that patient.	
R114	(4) Abide by all Federal and State laws regarding confidentiality and disclosure for patient care records and election information.	
R125	**§ 403.732 Condition of participation: Quality assessment and performance improvement.** The RNHCI must develop, implement, and maintain a quality assessment and performance improvement program.	Intent: §403.732 The facility must have in place a program that has a definitive scope and which can be used to measure, analyze, track, and improve performance. The plan should address the full range of services offered by the facility.
R126	(a) Standard: Program scope. (1) The quality assessment and performance improvement program must include, but is not limited to, measures to evaluate: (i) Access to care. (ii) Patient satisfaction. (iii) Staff performance. (iv) Complaints and grievances. (v) Discharge planning activities. (vi) Safety issues, including physical environment.	Guideline: §403.732 (a)(1) The facility must objectively evaluate the required areas. The facility must also objectively evaluate any additional areas which they decide to include in their quality assessment and evaluation program. Specifically, at a minimum, the facility must define and describe quality assessment and performance improvement activities that are appropriate for the services furnished in the facility. HCFA has not provided a specific definition of quality nor provides an outline for what activities are appropriate to meet this standard due to the unique nature of the RNHCI program.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R127	(2) In each of the areas listed in paragraph (a)(1) of this section, and any other areas the RNHCI includes, the RNHCI must do the following: (i) Define quality assessment and performance improvement measures. (ii) Describe and outline quality assessment and performance improvement activities appropriate for the services furnished by or in the RNHCI. (iii) Measure, analyze, and track performance that reflect care and RNHCI processes. (iv) Inform all patients, in writing, of the scope and responsibilities of the quality assessment and performance improvement program.	Procedure: §403.732(a)(2) Review facility policies and procedures on the quality assessment and performance improvement program. Determine if the facility has a formal method to identify issues in the facility, that require quality assessment and performance improvement. Determine if the facility has a method to respond to identified issues and the means to evaluate the response to the issues. Verify through interviews with staff, patients, and governing body member(s) that the facility has established a protocol or method for addressing quality in the facility, and those issues that the facility believes have now been resolved. Verify that the staff and patient know how to access that process.
R128	(3) The RNHCI must set priorities for performance improvement, considering the prevalence of and severity of identified problems.	Probe: §403.732 (a)(3) Are RNHCI improvement priorities based on problems identified and is performance improvement realistic or achievable based on the prevalence and severity of the problem? Are priorities specific to identified problems with timeline for measuring each objective? Are there demonstrable steps toward improvement?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R129	(4) The RNHCI must act to make performance improvements and must track performance to assure that improvements are sustained.	Guideline: §403.732(a)(4) The facility must use an objective means of tracking performance. Each facility is allowed the flexibility to identify its own measures of performance for the activities it identifies as priorities in its quality assessment and performance improvement strategy. The facility meets this requirement by conducting an analysis when adverse outcomes are identified and the facility takes action to sustain correction and improvement of the identified issue. For a RNHCI to consider that it is "doing better" is a subjective statement and is not an acceptable measure of performance. There must be some identifiable units of measurement that a knowledgeable person can distinguish as evidence of change. Probe: §403.732(a)(4) Does the RNHCI take action to enact long-term correction and improvement?
R130	(b) Standard: Program responsibilities. (1) The governing body, administration, and staff are responsible for ensuring that the quality assessment and performance improvement program addresses identified priorities in the RNHCI and are responsible for the development, implementation, maintenance, and performance improvement of assessment actions.	Probe: §403.732(b)(1) How does the RNHCI ensure that responsibilities for quality assessment are identified, performed and monitored with the goal of continuous performance improvement?
R131	(2) The RNHCI must include all programs, departments, functions, and contracted services when developing, implementing, maintaining, and evaluating the program of quality assessment and performance improvement.	Guideline: §403.732(b)(2) This includes all services provided under contract with outside agencies.
R140	**§ 403.734 Condition of participation: Food services** The RNHCI must have an organized food service that is directed and adequately staffed by qualified personnel.	Intent: §403.734 Food Service "Qualified personnel" is defined based on State and local laws for the provision of food services. Food service personnel must demonstrate safe food handling (see §403.734).

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R141	(a) Standard: Sanitary conditions. The RNHCI must furnish food to the patient that is obtained, stored, prepared, distributed, and served under sanitary conditions.	Guideline: §403.734(a) Sanitary conditions means storing, preparing, distributing, and serving food properly to prevent food-borne illness. Potentially hazardous foods must be subject to continuous time/temperature controls to prevent either the rapid and progressive growth of infectious or toxigenic micro-organisms, such as Salmonella, or the slower growth of Clostridium Botulinum. In addition, foods of plant origin become potentially hazardous when the skin, husk, peel, or rind is breached, thereby possibly contaminating the fruit or vegetable with disease-causing micro-organisms. Potentially hazardous food tends to focus on animal products, including but not limited to milk, eggs, and poultry. Improper holding temperature is a common contributing factor of food borne illness. The facility must follow proper procedures in cooking, cooling, and storing food according to time, temperature, and sanitary guidelines. Improper handling of food can cause Salmonella and E-coli contamination. The RNHCI is expected to follow accepted standards of practice in regards to food storage and handling. Procedure and Probe: §403.734(a) Observe storage, cooling, and cooking of food. Record the time and date of all observations. If a problem is noted, conduct additional observations to verify findings. Observe that employees are effectively cleaning their hands prior to preparing, distributing and serving food. Observe that food is covered to maintain temperature and protect from other contaminants when transporting meals to patients. Refrigerated storage: Check all refrigerators and freezers for temperatures. Use the facility's or the surveyor's own properly sanitized thermometer to evaluate the internal temperatures of potentially hazardous foods with a focus on the quantity of leftovers and the container sizes in which bulk leftovers are stored. Food preparation: Use a sanitized thermometer to evaluate food temperatures. In addition, how do kitchen staff process leftovers? Are they heated to the appropriate temperatures? How is frozen food thawed? How is potentially hazardous food handled during multi-step food preparation (e.g., chicken salad, egg salad)? Is hand contact with food minimized? Food service: Using a properly sanitized thermometer, check the temperature of hot and cold food prior to serving. How long is milk held without refrigeration prior to distribution? Food distribution: Is the food protected from contamination as it is transported to the dining rooms and residents' rooms? Are hand washing facilities convenient and properly equipped for dietary services staff use? (Staff uses good hygienic practices and staff with communicable diseases or infected skin lesions do not have contact with food if that contact will transmit the disease.) Are toxic items (such as insecticides, detergent, polishes) properly stored, labeled, and used separate from the food?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R141 (Cont.)		Probe: §403.734(a) Observe food storage rooms and food storage in the kitchen. Are containers of food stored off the floor and on clean surfaces in a manner that protects it from contamination? Are other areas under storage shelves monitored for cleanliness to reduce attraction of pest? Are potentially hazardous foods stored at 41º F or below and frozen foods kept at 0º F or below? Do staff handle and cook potentially hazardous foods properly? Are potentially hazardous foods kept at an internal temperature of 41º F or below in a cold food storage unit, or at an internal temperature of 140º F or above in a hot food storage unit during display and service? Is food transported in a way that protects against contamination (i.e., covered containers, wrapped, or packaged)? Is there any sign of rodent or insect infestation? (Dishwashing) The current 1993 Food Code, DHHS, FDA, PHS recommends the following water temperature and manual washing instructions: Machine: 1. Hot Water: a. 140º F Wash (or according to the manufacturer's specifications or instructions). b. 180º F Rinse (180º, 160º or greater at the rack and dish/utensils surfaces. 2. Low temperature: a. 120º F + 25ppm (parts per million) Hypochlorite (household bleach) on dish surface.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R142	(b) Standard: Meals. The RNHCI must serve meals that furnish each patient with adequate nourishment in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences. The RNHCI must do the following: (1) Furnish food that is palatable, attractive, and at the proper temperature and consistency.	Guideline and Probe: §403.734(b)(1) HCFA prohibits prescription of therapeutic diets or parenteral nutrition in this program, as these are considered medical practices. However, altering food consistency (mechanically altered food; chopped, cut, ground, pureed, etc.) is not considered a medical practice, but is designed to meet the needs of the patient. "Food-palatability" refers to the taste and/or flavor of the food. "Food-attractiveness" refers to the appearance of the food when served to patients. Evidence for palatability and attractiveness of food, from day to day and meal to meal, may be strengthened through sources such as additional observation, patient, and staff interviews. o Does food have a distinct aroma or odor? o Is the appearance varied in color and texture? o Is food generally well seasoned (use of spices, herbs, etc.), and acceptable to patients? Is food served at preferable temperature (hot foods are served hot and cold foods are served cold) as discerned by the patient and customary practice? Is food held and served at proper temperatures? Identify concerns such as appearance or meal quality (such as color and texture of vegetables or meats and, preparation and presentation of mechanically altered foods).
R143	(2) Offer substitutes of similar nourishment to patients who refuse food served or desire alternative choices.	Guidelines: §403.734(b)(2-4) Observe food service to determine that meals are appropriate to each patient according to care plans. Ask patients how well the food meets their taste needs. Are patients offered the opportunity to receive substitutes when refusing food on the original menu?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R144	(3) Furnish meals at regular times comparable to normal mealtimes in the community. There must be no more than 14 hours between a substantial evening meal and breakfast the following day.	Guideline: §403.734 (b) (2-4) Ask patients when they eat breakfast, lunch, and dinner.
R145	(4) The RNHCI must offer snacks at bedtime.	
R150	**§ 403.736 Condition of participation: Discharge planning.** The RNHCI must have in effect a discharge planning process that applies to all patients. The process must assure that appropriate post-institution services are obtained for each patient, as necessary.	Intent: §403.736 To assure appropriate discharge planning process is done on post-institution services.
R151	(a) Standard: Discharge planning evaluation. (1) The RNHCI must assess the need for a discharge plan for any patient identified as likely to suffer adverse consequences if there is no planning and for any other patient upon his or her request or at the request of his or her legal representative. This discharge planning evaluation must be initiated at admission and must include the following: (i) An assessment of the possibility of a patient needing post-RNHCI services and of the availability of those services.	Guidelines and Procedures: §403.736(a)(1 - 3) The discharge planning process must be initiated when the patient is admitted to the facility or upon request of the patient or legal representative. The discharge planning evaluation must include: o An assessment of the possibility of a patient needing services after discharge; o The patient's capacity for self-care; and o Information regarding the care in the environment from which he or she entered the facility and where he or she is going to after discharge. Although all patients must have a discharge planning evaluation, not all patients will require a discharge plan. Review discharge planning evaluations and review discharge plans as applicable.
R152	(ii) An assessment of the probability of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the RNHCI.	Procedure: §403.736 (a)(1)(ii) Review closed records for discharge planning and post-institution services. Interview facility staff involved in the discharge planning process.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R153	(2) The staff must complete the assessment on a timely basis so that arrangements for post-RNHCI care are made before discharge and so that unnecessary delays in discharge are avoided.	Guidelines and Procedures: §403.736(a)(1 - 3) Determine whether the assessment was timely and evaluated on a case-by-case basis. Assessments completed after discharge are not timely.
R154	(3) The discharge planning evaluation must be included in the patient's rights record for use in establishing an appropriate discharge plan and must discuss the results of the evaluation with the patient or a legal representative acting on his or her behalf.	Guidelines and Procedures: §403.736(a)(1 - 3) Changes in the discharge plan during a patient's stay in the facility must also be discussed and understood by the patient and/or legal representative.
R155	(b) Standard: Discharge plan. (1) If the discharge planning evaluation indicates a need for a discharge plan, qualified and experienced personnel must develop or supervise the development of the plan.	Guideline and Probe: §403.736(b)(1) The RNHCI is responsible for identifying the qualified and experienced person(s) for developing or supervising a discharge plan. Does the person have knowledge of community resources? Does the person have experience in addressing home care needs?
R156	(2) In the absence of a finding by the RNHCI that the beneficiary needs a discharge plan, the beneficiary or his or her legal representative may request a discharge plan. In this case, the RNHCI must develop a discharge plan for the beneficiary.	Guidelines and Probes: §403.736(b)(2 - 5) Is there evidence of discharge planning evaluation in all sampled records? If a patient is determined to need a discharge plan, is one developed? Is a discharge plan developed if the patient or legal representative requests one?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R157	(3) The RNHCI must arrange for the initial implementation of the beneficiary's discharge plan.	Guidelines and Probes: §403.736(b)(2 - 5) Are discharge plans modified to reflect current patient status and needs? Do discharge plans address necessary post-discharge care? How does the facility inform patients or legal representatives about post-RNHCI care requirements? Determine whether the facility notifies family members or legal representatives of proposed transfers or discharges.
R158	(4) If there are factors that may affect continuing care needs of the appropriateness of the discharge plan, the RNHCI must reevaluate the beneficiary's discharge plan.	
R159	(5) The RNHCI must inform the beneficiary or legal representative about the beneficiary's post-RNHCI care requirements.	
R160	(6) The discharge plan must inform the beneficiary or his or her legal representative about the freedom to choose among providers of care when a variety of providers is available that are willing to respect the discharge preferences of the beneficiary or legal representative.	Probe: §403.736(b)(6) How does the facility incorporate advance directives, elections and revocation of elections into the discharge plan? How does the facility inform patients or legal representatives of their choices regarding other care providers and settings? How does the facility inform patients and legal representatives about the details of the election and revocation of the election process and involve the patient in decisions? (See §403.724 Valid Election Requirements.)
R161	(c) Standard: Transfer or referral. The RNHCI must transfer or refer patients in a timely manner to another facility (including a medical facility if requested by the beneficiary, or his or her legal representative) in accordance with §403.730 (b)(2)	Probe: §403.736(c) Does the RNHCI demonstrate timely referral? Are there policy and procedures for emergency situations, transfers, and/or referrals?
R162	(d) Standard: Reassessment. The RNHCI must reassess its discharge planning process on an ongoing basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.	Probe: §403.736(d) What is the facility process to assess its discharge planning evaluation activities on an ongoing basis? How has the facility responded to changing discharge planning needs? Has the reassessment included reviewing a sampling of discharge plans and follow up with the patient.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R175	**§403.738 Condition of participation: Administration.** An RNHCI must have written policies regarding its organization, services, and administration. (a) Standard: Compliance with Federal, State, and local laws. The RNHCI must operate in compliance with all applicable Federal, State, and local laws, regulations, and codes including, but not limited to, those pertaining to the following:	Procedures: §403.738(a)(1-3) Determine whether the facility is in compliance with Federal, State and local laws.
R176	(1) Protection against discrimination on the basis of race, color, national origin, age, or handicap (45 CFR parts 80, 84, and 91).	
R177	(2) Protection of human research subjects (45 CFR part 455).	
R178	(3) Application of all safeguards to protect against the possibility of fraud and abuse (42 CFR part 455).	
R179	(b) Standard: Governing body. (1) The RNHCI must have a governing body, or a person designated to function as a governing body, that is legally responsible for establishing and implementing all policies regarding the RNHCI's management and operation.	Guideline: §403.738(b)(1) The governing body provides, monitors, and revises, as necessary, policies and operating directions that ensure the necessary staffing, training resources, equipment and environment to provide patients care and ensure their health and safety. How does the governing body exercise its responsibility for the entire operation of the RNHCI and evaluation of the RNHCI and its patients' outcomes? The responsibility for direction includes areas such as health, safety, sanitation, maintenance and repair, and utilization and management of staff. When deficiencies are identified during the survey, interview the administrator or review the minutes of governing body meetings, if available, to determine to what extent the governing body has identified and attempted to address the problem. If staff have been trained, but are not implementing programs or are inappropriately deployed (e.g., there are enough staff but they are assigned to duties like record keeping which revents them from delivering needed services), this may indicate a failure of the governing body to adequately direct staff activities.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R180	(2) The governing body must appoint the administrator responsible for the management of the RNHCI.	Guideline: §403.738(b)(2) Review agreements with outside agencies to ensure that entities entering into affiliations with the RNHCI for purposes of management and operations meet the ownership requirements at §403.720(a)(7) and §403.738(c).
R181	(c) Standard: Affiliations and disclosure. (1) An affiliation is permissible if it is between one of the following: (i) An individual serving as an uncompensated director, trustee, officer, or other member of the governing body of an RNHCI and a provider of medical treatment or services. (ii) An individual who is a director, trustee, officer, employee, or staff member of an RNHCI and another individual, with whom he or she has a family relationship, who is affiliated with (or has an ownership interest in) a provider of medical treatment or services. (iii) The RNHCI and an individual or entity furnishing goods or services as a vendor to both providers of medical treatment or services and RNHCIs.	
R182	(2) The RNHCI complies with the disclosure requirements of §§ 420.206 and 455.104 of this chapter.	
R183	(3) The RNHCI furnishes written notice, including the identity of each new individual or company, to HCFA at the time of a change, if a change occurs in any of the following: (i) Persons with an ownership or control interest, as defined in §§ 420.201 and 455.101 of this chapter.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R183 (Cont.)	(ii) The officers, directors, agents, or managing employees. (iii) The religious entity, corporation, association, or other company responsible for the management of the RNHCI. (iv) The RNHCI's administrator or director of nonmedical nursing services.	
R190	**§403.740 Condition of participation: Staffing.** The RNHCI must be staffed with qualified experienced personnel who are present in sufficient numbers to meet the needs of the patients.	Intent: §403.740 The intent of the regulation is that all areas of the RNHCI are staffed with sufficient, qualified personnel. To be an efficient and well-run institution, all staff, including those not directly involved in patient care, must work to improve the overall quality of the facility. Staff are available and know how to respond to individual patients' needs and emergencies at all times. The RNHCI has sufficient staff to provide needed care and services. Guideline: §403.740 The test of adequacy of staffing is how well the facility has organized itself to detect and react appropriately to potential emergencies, such as fire, injuries, etc. Do not look at numbers alone. The RNHCI is responsible for organizing and evaluating its activities, assignments and available staff in such a way that maximizes the benefit to the patient. During the course of the onsite survey, you should be able to observe behavioral evidence of such organization. Probe: §403.740 Is there observational or other evidence to suggest that patients' needs are not being met (e.g., demonstrate need for toileting, changing) while staff do laundry, housekeeping, cooking, or other tasks?
R191	(a) Standard: Personnel qualifications. The RNHCI must ensure that staff who supervise or furnish services to patients are qualified to do so and that staff allowed to practice without direct supervision have specific training to furnish these services.	Guideline: §403.740(a) In order to determine whether RNHCI staff are "qualified," in the absence of specific Federal, State, or local laws, review staff records for evidence of work experience and training (including, but not limited to, educational or life experience) with respect to duties currently performed. This standard applies to all such individuals who furnish services, whether or not they are employed or compensated by the RNHCI or, if they are compensated, whether salaried or contractors.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R192	(b) Standard: Education, training, and performance evaluation. (1) The RNHCI must ensure that staff (including contractors and other individuals working under arrangement) have the necessary education and training concerning their duties so that they can furnish services competently. This education includes, but is not limited to, training related to the individual job description, performance expectations, applicable organizational policies and procedures, and safety responsibilities.	Probe: §403.740(b)(1) How does the facility orient personnel (including contractual personnel) to RNHCI objectives, policies, procedures, and programs? How does coordination of care among staff and/or contract personnel providing services to the facility occur? Have staff received training (both upon hiring and on an ongoing basis) which results in the competencies needed to do their job? Are staff aware and capable of meeting their job requirements?
R193	(2) Staff must demonstrate, in practice, the skills and techniques necessary to perform their duties and responsibilities.	Guidelines: § 403.740(b)(2) and (3) For effective service and safety of the patients, it is critical that all staff use the skills and techniques necessary to do their jobs correctly. Procedures and Probes: § 403.740(b)(2) and (3) Observe whether or not staff are knowledgeable about the needs of each patient with whom they are assigned to work. Staff should be able to demonstrate in practice the results of training for the patients for whom they are responsible. Determine the extent to which staff demonstrate competency in providing care for the patients for whom they are responsible. If you identify questionable patient care practices by staff: - Interview staff with respect to the practice; and - Determine the purpose of the practice. How has the facility addressed areas of weakness identified in its evaluation of its staff and incorporated actions to improve staff and the facility's overall performance? How does the facility orient personnel (including contractual personnel) to objectives, policies, procedures, and programs? How does coordination of care among staff and/or contract personnel providing services to the facility occur on an ongoing basis?
R194	(3) The RNHCI must evaluate the performance of staff and implement measures for improvement.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R200	**§403.742 Condition of participation: Physical environment.** A RNHCI must be designed, constructed, and maintained to ensure the safety of the patients, staff, and the public. (a) Standard: Buildings. The physical plant and the overall environment must be maintained in a manner that ensures the safety and well-being of the patients. The RNHCI must have the following:	Guidelines: §403.742(a)(1-2) "Emergency power" includes, at a minimum, battery-operated lighting for entrances and exits, fire detection and alarm systems, and fire extinguishing systems. Review results of inspections by the designated fire safety authority (where applicable) demonstrating that the emergency power system has been tested periodically and is functioning in accordance with the Life Safety Code. Check placement of lighting systems to ensure proper coverage of affected areas. Test all batteries to ensure they work. Make sure that patients do not have access to soiled diapers, linens, bandages, or any other potentially infectious materials. These materials must be handled in a manner which prevents leakage from containers by exposure to the general environment.
R201	(1) Emergency power for emergency lights, for fire detection and alarm systems, and for fire extinguishing systems.	
R202	(2) Procedures for the proper storage and disposal of trash.	
R203	(3) Proper ventilation and temperature control and appropriate lighting levels to ensure a safe and secure environment.	Guidelines and Probes: §403.742(a)(3-5) "Proper ventilation" is good air circulation, avoidance of drafts at floor level, and adequate smoke exhaust removal. Air temperatures in the facility should be comfortable in most circumstances. In extremely hot or cold weather, precautions are taken by the facility to protect individuals from ill-effects of temperature. "Appropriate lighting levels" are light levels which meet patient needs. How does the facility regulate temperature, ventilation, and lighting? Is there good air movement? Are patient areas ventilated? What does the facility do to accommodate temperature, lighting, and ventilation to meet patient needs?
R204	(4) A written disaster plan to address loss of power, water, sewage, and other emergencies.	
R205	(5) Facilities for emergency gas and water supply.	
R206	(6) An effective pest control program.	Guideline: §403.742(a)(6) Look for signs of pests such as mice, roaches, rats, and flies. Is the area pest free?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R207	(7) A preventive maintenance program to maintain essential mechanical, electrical, and fire protection equipment operating in an efficient and safe manner.	
R208	(8) A working call system for patients to summon aid or assistance.	
R209 R210 R211	(b) Standard: Patient rooms. Patient rooms must be designed and equipped for adequate care, comfort, and privacy of the patient. (1) Patient rooms must meet the following conditions: (i) Accommodate no more than four patients. (ii) Measure at least 80 square feet per patient in multiple patient rooms and at least 100 square feet in single patient rooms.	Guideline: §403.742(b)(1)(ii) The measurement of the square footage should be based upon the useable living space of the room. Therefore, the minimum square footage in patient rooms should be measured based upon the floor's measurements exclusive of toilets and bath areas, closets, lockers, wardrobes, alcoves, or vestibules. However, if the height of the alcoves or vestibules reasonably provides useful living area, then the corresponding floor area may be included in the calculation. The space occupied by movable wardrobes should be excluded from the useable square footage in a room, unless it is an item of the patient's own choice, and it is in addition to the individual closet space in the patient's room. Non-permanent items of the patient's own choice should have no effect in the calculation of useable living space. Protrusions such as columns, radiators, ventilation systems for heating and/or cooling should be ignored in computing the useable square footage of the room if the area involved is minimal (e.g., a baseboard heating or air conditioning system or ductwork that does not protrude more than 8 inches from the wall, or a column that is, not more than 8 inches on each side), and does not have an adverse effect on the patient's health and safety. If these protrusions are not minimal, they would be deducted from useable square footage computed in determining compliance with this requirement. The swing or arc of any door that opens directly into the patient's room should not be excluded from the calculations of useable square footage in a room. The facility layout may give square footage measurements. Carry a tape measure and take measurements if the room appears small. Unless a variance has been applied for and approved as at § 403.742(b)(3), are there at least 80 square feet per patient in multiple patient rooms and at least 100 square feet for single patient rooms? Additional guidance is available from the Life Safety Code (LSC) specialist.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R212	(iii) Have direct access to an exit corridor.	Guideline: §403.742(b)(1)(iii) There is no authority under current regulations to approve a variance to this requirement.
R213	(iv) Be designed or equipped to assure full visual privancy for each patient.	Guideline: §403.742(b)(1)(iv) "Full visual privacy" means that patients have a means of completely withdrawing from public view while occupying their bed (e.g., curtain, moveable screens, private room). The guidelines do not intend to limit the provisions of privacy to solely one or more curtains, moveable screens or a private room. Facility operators are free to use other means to provide full visual privacy, with those means varying according to the needs and requests of patients. However, the requirement explicitly states that bedrooms must "be designed or equipped to assure full visual privacy for each patient." For example, a patient with a bed by the window cannot be required to remain out of his or her room while his/her roommate is having a dressing changed. Room design or equipment must provide privacy. Procedure: §403.742(b)(1)(iv) Surveyors will assess whether the means the facility is using to assure full-visual privacy meets this requirement without negatively affecting any other patient rights.
R214	(v) Have at least one window to the outside.	
R215	(vi) Have a floor at or above grade level.	
	(2) The RNHCI must furnish each patient with the following:	Guideline: §403.742(b)(2)(iv) "Functional furniture appropriate to the patients' needs" means that the furniture in each patient's room contributes to the patient attaining or maintaining his/her highest practicable level of independence. In general, furnishings include places to put clothing away in an organized manner that will let it remain clean, free of wrinkles, and accessible to the patient while protecting it from casual access by others, and places to put personal effects. There may be instances in which individual patients determine that certain items are not necessary (e.g., both the patient and spouse use wheelchairs. They visit more easily without another chair in the room.) In this case, the patient's wishes should determine the furniture needs. "Shelves accessible to the patient" means that the patient, if able, or a staff person at the direction of the patient, can get to their clothes whenever they choose. Probe: §403.742(b)(2)(iv) Is there functional furniture appropriate to the patients' needs? Is there individual closet space with accessible clothes racks and shelves?
R216	(i) A separate bed of proper size and height for the convenience of the patient.	
R217	(ii) A clean, comfortable mattress.	
R218	(iii) Bedding appropriate to the weather and climate.	
R219	(iv) Functional furniture appropriate to the patient's needs and individual closet space with clothes racks and shelves accessible to the patient.	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R220	(3) HCFA may permit variances in requirements specified in paragraphs (b)(1)(i) and (ii) of this section relating to rooms on an individual basis when the RNHCI adequately demonstrates in writing that the variances meet the following: (i) Are in accordance with the special needs of the patients. (ii) Will not adversely affect patients' health and safety.	Guideline: §403.742(b)(3) A variance must be in accordance with the special needs of the patients and must not adversely affect the health or safety of patients. Facility hardship is not part of the basis for granting a variance. Procedure: §403.742(b)(3) The variances must be reviewed and considered for renewal whenever the facility is certified.
R225	**§403.744 Condition of participation: Life safety from fire.** (a) General. An RNHCI must meet the following conditions:	Guideline: § 403.744 (a)(1) A waiver of specific provisions of the Life Safety Code is reviewed each time a facility is certified. The State fire authority will determine if the waiver continues to be justified, in that compliance with the requirement would result in an unreasonable hardship upon the facility and does not adversely affect the health and safety of patients or personnel. The State fire authority will forward its findings and recommendation as soon as possible to HCFA Region I for a decision on granting a waiver. The survey for safety from fire is normally conducted by the designated State fire authority. HCFA Region I must establish a procedure for the State fire authority to notify them whether the facility is or is not in compliance with the requirement. If the survey team observes fire hazards or possible deficiencies in life safety from fire, they must notify the designated State fire authority and Region I.
R226	(1) Except as provided in paragraph (b) of this section, the RNHCI must meet the new or existing health care occupancies provision of the 1997 edition of the Life Safety Code of the National Fire Protection Association (NFPA 101), which is incorporated by reference. Incorporation by reference of NFPA 101, the Life Safety Code, 1997 edition, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.[1] (See §483.70)	

[1]The 1997 edition of the Life Safety Code (NFPA 101) is available for inspection at the HCFA Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD, and at the Office of the Federal Register, 800 North Capitol Street, N. W., Suite 700, Washington, D. C. Copies of this publication may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P. O. Box 9101, Quincy, MA 02263-9101.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R227	(2) The RNHCI must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, staff, and the public; evacuation; and cooperation with fire fighting authorities.	
R228	(3) The RNHCI must maintain written evidence of regular inspection and approval by State or local fire control agencies. (b) Exceptions. (1) If application of the Life Safety Code required under paragraph (a)(1) of this section would result in unreasonable hardship upon the RNHCI, HCFA may waive specific provisions of the Life Safety Code, but only if the waiver does not adversely affect the health and safety of patients. (2) If HCFA finds that the fire and safety code imposed by State law adequately protects patients in the institution, the provisions of the Life Safety Code required in paragraph (a)(1) of this section do not apply in that State.	
R235	**§403.746 Condition of participation: Utilization review**. The RNHCI must have in effect a written utilization review plan to assess the necessity of services furnished. The plan must provide that records be maintained of all meetings, decisions, and actions by the utilization review committee.	Guideline: § 403.746 Determine that the RNHCI has a written utilization review plan to assess the necessity of services furnished by the RNHCI and its staff to Medicare and Medicaid patients. Verify through review of records and reports, and interviews with the Utilization Review (UR) chairperson and/or members, that UR activities are being performed as described in the plan. Review the minutes of the UR committee to verify that they include procedures for evaluating admissions as stated in § 403.746(a).

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
R236	(a) Standard: Utilization review plan. The utilization review plan must contain written procedures for evaluating the following: (1) Admissions. (2) Duration of care. (3) Continuing care of an extended duration. (4) Items and services furnished.	
R237	(b) Standard: Utilization review committee. The committee is responsible for evaluating each admission and ensuring that the admission is necessary and appropriate. The utilization review plan must be carried out by the utilization review committee, consisting of the governing body, administrator or other individual responsible for the overall administration of the RNHCI, the supervisor of nursing staff, and other staff as appropriate.	Guideline: §403.746(b) Review the Utilization Review plan and the determinations involving all admissions or extended stays. Verify that the composition of the UR committee is appropriate.

APPENDIX V

INTERPRETIVE GUIDELINES AND INVESTIGATIVE PROCEDURES FOR RESPONSIBILITIES OF MEDICARE PARTICIPATING HOSPITALS IN EMERGENCY CASES

Investigation Procedures for Responsibilities of Medicare Participating Hospitals in Emergency Cases

PART 1

Interpretive Guidelines for Responsibilities of Medicare Participating Hospitals in Emergency Cases

PART 2

I. GENERAL INFORMATION

Medicare participating hospitals must meet the anti-dumping regulations in 42 CFR 489.24 and the related requirements at 42 CFR 489.20(l), (m), (q), and (r). These regulations prohibit hospitals with emergency departments from refusing to examine or to treat medically unstable patients. The term "hospital" includes rural primary care hospitals. The provisions of this regulation apply to all individuals (not just Medicare beneficiaries) who attempt to gain access to a hospital for emergency care. The regulations define "hospital with an emergency department" to mean a hospital that offers services for emergency medical conditions within its capability to do so.

Hospitals providing emergency services are required to take the following measures:

o Adopt and enforce policies and procedures to comply with the requirements of 42 CFR 489.24;

o Post signs in the emergency department specifying the rights of individuals with emergency medical conditions and women in labor who come to the emergency department for health care services, and indicate on the signs whether the hospital participates in the Medicaid program;

o Maintain medical and other records related to individuals transferred to and from the hospital for a period of five years from the date of the transfer;

o Maintain a list of physicians who are on call to provide treatment necessary to stabilize an individual with an emergency medical condition;

o Maintain a central log on each individual who comes to the emergency department seeking treatment and indicate whether the individual:

- Refused treatment,
- Was refused treatment,
- Was transferred, admitted and treated, or stabilized and transferred, or
- Was discharged;

o Provide for an appropriate medical screening examination;

o Provide necessary stabilizing treatment for emergency medical conditions and labor;

o Provide an appropriate transfer of an unstabilized patient to another medical facility if:

- The patient (or a person acting on his or her behalf) after being informed of the risks and the hospital's obligations, requests a transfer,
- A physician has signed the certification that the benefits of the transfer of the patient to another medical facility outweigh the risks, and

- A qualified medical person (as determined by the hospital in its by-laws or rules and regulations) has signed the certification after a physician, in consultation with that qualified medical person, has made the determination that the benefits of the transfer outweigh the risks and the physician subsequently in a timely manner countersigns the certification. (This last criterion applies if the responsible physician is not physically present in the emergency department at the time the individual is transferred.)

o Provide treatment to minimize the risks of transfer;

o Send all pertinent records to the receiving hospital;

o Obtain the consent of the receiving hospital to accept the transfer;

o Ensure that the transfer of an unstabilized patient is effected through qualified personnel and transportation equipment, including the use of medically appropriate life support measures;

o Not delay medical screening, examination and/or stabilizing treatment in order to inquire about payment status;

o Accept appropriate transfers of patients with medical emergencies if the hospital has specialized capabilities or facilities and has the capacity to treat those individuals; and

o Not penalize or take adverse action against a physician or a qualified medical person because the physician or qualified medical person refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized, or against any hospital employee who reports a violation of these requirements.

Hospitals that violate the provisions in 42 CFR §489.24 or the related requirements in 42 CFR 489.20(l), (m), (q), and (r) are subject to termination.

A hospital is required to report to HCFA or to the State survey agency promptly when it suspects it may have received an improperly transferred individual. The receiving (recipient) hospital must report to HCFA or to the State survey agency any suspected incidents. Failure to report improper transfers may subject the receiving hospital to termination of its provider agreement.

To assure that HCFA is aware of all instances of improper transfers or potential violations of the other anti-dumping requirements, the State survey agencies must promptly report to the RO all complaints related to violations of 42 CFR 489.24 and the related requirements at 42 CFR 489.20(l), (m), (q), and (r). The RO will decide whether a complaint alleges a violation of these requirements and warrants an investigation.

Section 42 CFR 489.53(a)(2) prohibits providers from placing restrictions on Medicare admissions that are different from those placed on non-Medicare admissions. To do so is a basis for termination of the Medicare provider agreement.

If the hospital does not have an emergency department as defined in 42 CFR 489.24(b), apply 42 CFR 482.12(f)(2) which requires the hospital's governing body to assure that the medical staff has written policies and procedures for appraisal of emergencies and the provision of initial treatment and referral (Form HCFA-1537, Medicare/Medicaid Hospital Survey Report).

Quality of care review performed either by the SA or other physicians must not delay processing of a substantiated violation of the screening, treatment, transfer, or reporting requirements of this regulation. If, during the course of the investigation, you identify possible quality of care issues other than those related to the provisions of this regulation, obtain a copy of the patient's medical record and send the case to the RO for referral to the appropriate Peer Review Organization. Contact the RO if the hospital refuses to provide a copy of the medical record.

If you suspect emergency services are being denied based on diagnosis (e.g., AIDS), financial status, race, color, national origin, or handicap, refer the cases to the RO. The RO will forward the cases to the Office of Civil Rights (OCR) for investigation of discrimination.

A hospital must formally determine who is qualified to perform the initial medical screening examinations, i.e., qualified medical person. The delegation must be set forth in a document that is approved by the governing body of the hospital. The delegation may be located in the hospital by-laws, or in the rules and regulations governing the medical staff if they have been approved by the governing body. It is not acceptable for the hospital to allow the medical director of the emergency department to make what may be informal delegations that could frequently change.

If it appears that a hospital with an emergency department does not have adequate staff and equipment to meet the needs of patients, expand the investigation to survey for compliance with the requirements of 42 CFR 482.55.

Look for evidence that the procedures and policies for emergency medical services (including triage of patients) are established, evaluated, and updated on an ongoing basis.

The hospital should have procedures which assure integration with other hospital services, including laboratory, radiology, and operating room services (if provided), to provide continuity of care.

II. PRINCIPAL FOCUS OF INVESTIGATION

Investigate for compliance with the regulations in 42 CFR 489.24 and the related requirements in 42 CFR 489.20(l), (m), (q), and (r). All investigations are to be unannounced. The investigation is based on an allegation of noncompliance. The purpose of the investigation is to ascertain whether a violation took place, to determine whether the violation constitutes an immediate and serious threat to patient health and safety, to identify any patterns of violations at the facility, and to assess whether the facility has policies and procedures to address the provisions of the anti-dumping law.

The focus of the investigation is on the initial allegation of violation and the discovery of additional violations. If the allegation is not confirmed, the surveyor must still be assured that the hospital's policies and procedures, physician certifications of transfers, etc., are in compliance with the requirements of 42 CFR 489.24 and the related requirements at 42 CFR 489.20(l), (m), (q), and (r). If the allegations are confirmed, the investigation would continue, but with an emphasis on the hospital's compliance within the last six months.

Ensure that the case(s), if substantiated, is (are) fully documented on Form HCFA-2567, Statement of Deficiencies and Plan of Correction. The investigation should be completed within ten days of the RO authorization if it appears there may be a violation of §§1866 and 1867 of the Act. If there appears to be a violation, and conditions of participation are felt to have been met, the time frame may be extended to 15 days.

Once the complaint is received the RO is strongly encouraged to share as much information with the hospital as possible according to the Privacy Act regarding the complaint and investigation with the providers being investigated. The RO may also include any facts of the alleged actual violation, a

copy of any medical review done (the identity of the reviewer must be deleted), and the identity of the patient involved (not the identity of the complainant or source of the complaint). HCFA will determine if the alleged violation constitutes an immediate and serious threat to patient health and safety.

The hospital has the opportunity to present evidence to HCFA that it believes demonstrates its compliance, and the opportunity to comment on evidence HCFA believes demonstrates the hospital's noncompliance. Hospitals should also be able to seek clarification of policy prior to and after an action. HCFA's regional offices retain delegated enforcement authority, and final enforcement decisions are made there.

III. TASK 1 - ENTRANCE CONFERENCE

A brief entrance conference must be held with the CEO/president of the hospital (or his or her designee) and any other staff the CEO considers appropriate to explain the nature of the allegation, the purpose of the investigation, and the requirements against which the complaint will be investigated. The identity of the complainant and patient must always be kept confidential unless written consent is obtained. Ask the CEO to have the staff provide you with the following information (as appropriate):

- A log of emergency department cases for the past 6-12 months;
- The emergency department policy/procedures manual (review triage and assessment of patients presenting to the emergency department with emergency medical conditions, assessment of labor, transfers of individuals with emergency medical conditions, etc.);
- Consent forms for transfers of unstable individuals;
- Emergency department committee meeting minutes for the past 12 months;
- Emergency department staffing schedule (physicians for the past 3 months and nurses for the last 4 weeks);
- Bylaws/rules and regulations of the medical staff;
- Minutes from medical staff meetings for the past 6-12 months;
- Current medical staff roster;
- Physician on-call lists for the past six months;
- Credential files (to be selected by you) include the director of the emergency department and emergency department physicians. Review of credentials files is optional. However, if there has been a turnover in significant personnel (e.g., the Emergency Department (ED) director) or an unusual turnover of ED physicians, or a problem is identified during record review of a particular physician's screening or treatment in the ER, credentials files should be obtained and reviewed;
- Quality assurance plan;
- Quality assurance minutes (request which portion of the quality assurance minutes and plan which specifically relates to dumping regulations. If a problem is identified that would require a more thorough review, additional portions of the quality assurance plan and minutes may be requested for review);

o List of contracted services (request this list if a potential violation of §§1866 and 1867 of the Act is noted during the investigation and the use of contracted services is questioned);

o Emergency department personnel records (optional);

o In-service training program records, schedules, reports, etc. (optional: review if questions arise through interview and record review regarding the staff's knowledge of 42 CFR 489.24);

o Ambulance trip reports and memoranda of transfer, if available (to be selected by you if the cases you are reviewing concern transfers); and

o Ambulance ownership information.

In addition, if the case you are investigating occurred prior to the time frames mentioned, examine the above records for a three-month period surrounding the date of the alleged violation.

Inform the CEO that you will be selecting a sample of cases (medical records) for review from the emergency department log and that you will require those records in a timely fashion.

IV. TASK 2 - CASE SELECTION METHODOLOGY

The purpose of the sample is to identify additional violations and/or patterns of violations, if any, and to determine if patterns of patient dumping exist. Keep in mind, however, that a single occurrence is considered a violation.

A. Sample Size.--Select 20-50 records to review in depth, using the selection criteria described below. The sample is not intended to be a statistically valid sample and should be focused on potential problem areas. The sample size should be expanded as necessary in order to adequately investigate possible violations or patterns of deficiencies.

B. Sample Selection.--The sample of records reviewed will vary based on the nature of the complaint and the types of patients requesting emergency services. Do not allow the facility staff to select the sample. Use the emergency department log and other appropriate information, such as patient charts, to identify:

o Patients transferred to other facilities;

o Gaps, return cases, or nonsequential entries in the log;

o Refusals of examination, treatment, or transfer;

o Patients leaving against medical advice, and

o Patients returning to the emergency department within 48 hours.

Sample selection requires that:

1. You identify the number of emergency cases seen per month for each of the six months preceding the survey. Place this information on Form HCFA-1541B, Responsibilities of Medicare Participating Hospitals in Emergency Cases Investigation Report (Exhibit 137).

2. You identify the number of transfers of emergency patients to other acute care hospitals per month for each of the preceding six months. Review in-depth, transfers of patients where it appears that the transferring hospital could have provided continuing medical care. Place this information on Form HCFA-1541B.

3. You include the complaint case(s) in the sample, regardless of how long ago it occurred. Select other cases at the time of the complaint in order to identify patterns of hospital behavior and to help protect the identity of the complainant.

4. If the complaint case did not involve an inappropriate transfer (e.g., the complaint was for failure to provide an adequate screening examination, or a hospital with specialized capabilities refused an appropriate transfer), identify similar cases and review them.

5. If you identify additional violations, determine, if possible, whether there is a pattern related to:

- o Diagnosis (labor, AIDS);
- o Race;
- o Color;
- o Type of health insurance (Medicaid, uninsured, under-insured, or managed care);
- o Nationality; or
- o Handicap.

Any patterns are documented on Form HCFA-2567, Statement of Deficiencies and Plan of Correction, under the data tag number that corresponds with the violated responsibility. Place the number of substantiated violations on Form HCFA-1541B.

Document information concerning your sample selection on a blank sheet of paper or SA worksheet and label it "Summary Listing of Sampled Cases." Include the dates the individuals requested services, any identifier codes used to protect the individual's confidentiality, and the reasons for your decision to include these individuals in your sample.

V. TASK 3 - RECORD REVIEW

While surveyors may make preliminary findings during the course of the investigation, the appropriateness of the medical screening, examination, stabilizing treatment, and transfer must usually be determined by a physician. Because expert medical review is usually necessary, obtain copies of the medical and other record(s) of the alleged violation case (both hospitals if an individual sought care at two hospitals or was transferred) and any other violation cases identified in the course of the investigation.

Also, review documents pertaining to quality assurance activities in the emergency department and remedial actions taken in response to a violation of these regulations. Document hospital corrective actions taken prior to the survey and take such corrective action into account when developing your recommendation to the RO.

In an accredited hospital, if it appears that a Condition of Participation is not met, contact the RO for authorization to extend the investigation. If you are conducting the investigation in a nonaccredited hospital, you may expand the investigation to include other conditions without contacting the RO first. When there is insufficient information documented on the emergency record regarding a request for emergency care, it may be helpful to interview hospital staff, physicians, witnesses, ambulance personnel, the individual, or the individual's family. Ask for RO guidance if you are still unable to obtain a consistent and reliable account of what happened.

Any time delivery of a baby occurs during transfer, obtain a copy of all available records and refer the case for review by a physician approved by the RO.

If you are unsure whether qualified personnel and/or transportation equipment were used to effectuate a transfer, review the hospital's transfer policies, and obtain a copy of the medical record and transfer records. You may also need to review documentation and/or interview staff from the receiving facility about the transfer, and request physician review.

In cases where treatment is rendered to stabilize an emergency medical condition, the medical records should reflect the medically indicated treatment necessary to stabilize it, the medications, treatments, surgeries and services rendered, and the effect of treatment on the individual's emergency condition or on the woman's labor and the unborn child.

The medical records should contain documentation of medically indicated screens, tests, mental status evaluations, impressions, and diagnoses (supported by a history and physical examination, laboratory, and other test results).

For pregnant women, the medical records should show evidence that the screening examination included ongoing evaluation of fetal heart tones, regularity and duration of uterine contractions, fetal position and station, cervical dilation, and status of the membranes, i.e., ruptured, leaking, intact.

For individuals with psychiatric symptoms, the medical records should indicate an assessment of suicide or homicide attempt or risk, disorientation, or assaultive behavior that indicates danger to self or others.

In cases where an individual (or person acting in the individual's behalf) withdrew the initial request for a medical screening, examination and/or treatment for an emergency medical condition and demanded his or her transfer, or demanded to leave the hospital, look for a signed informed refusal of examination and treatment form by either the individual or a person acting in the individual's behalf. If the individual (or person acting in the individual's behalf) refused to sign the consent form, look for documentation by the hospital personnel that states that the individual refused to sign the form.

Examine the ambulance trip reports in questionable transfer cases (if available). These records can answer questions concerning the appropriateness of a transfer and the stability of the patient during the transfer.

Appropriate record review should also be conducted at the receiving (or recipient) hospital if the allegation case and any other suspicious transfer cases involve the transfer or movement of the individual to another hospital.

Document all significant record review findings in the complaint investigation narrative.

VI. TASK 4 - INTERVIEWS

To obtain a clear picture of the circumstances surrounding a suspected violation of the special responsibilities of Medicare hospitals in emergency cases, it is necessary to interview facility staff. For example, you may be able to gather a great deal of information from the admitting clerk in the emergency department, the nurses on shift at the time the individual sought treatment, and the quality assurance director of the hospital, to name a few. You may also need to interview witnesses, the patient, and/or the patient's family. The physician(s) involved in the incident should be interviewed.

Document each interview you conduct on a blank sheet of paper or SA worksheet and label it "Summary of Interviews." Include the following information, as appropriate, in your notes for each interview:

- o The individual's job title and assignment at the time of the incident;
- o Relationship to the patient and/or reason for the interview; and
- o Summary of the information obtained.

Appropriate interviews should also be conducted at the receiving hospital in cases of transfer or movement of the individual to another hospital.

Tag the interviews and submit them to the PRO or other physician reviewer.

VII. TASK 5 - EXIT CONFERENCE

The purpose of the exit conference is to inform the hospital of the scope of the investigation, including the nature of the complaint, investigation tasks, requirements investigated, and any hospital Conditions of Participation surveyed. Explain to the hospital staff the consequences of a violation of the requirements in 42 CFR 489.24 or the related requirements in 42 CFR 489.20(l),(m),(q), and (r) and the time frames that will be followed if a violation is found. Do not tell the hospital whether or not a violation was identified since it is the responsibility of the RO to make that determination. Inform the CEO (or his or her designee) that the RO will make the determination of compliance based on the information collected during this investigation and any additional information acquired from physician review of the case (if the RO determines that the medical issues of the case are beyond its expertise). Do not leave a draft of the deficiencies on Form HCFA-2567 with the hospital. Inform the hospital that the RO will send that information to the hospital once it is complete.

VIII. TASK 6 - PROFESSIONAL MEDICAL REVIEW

The purpose of professional medical review (physician review) is to provide peer review using information available to the hospital at the time the alleged violation took place. Physician review is needed to determine if:

- o The screening examination was appropriate. Physician review is not necessary when the hospital did not screen the individual;
- o The patient had an emergency medical condition. The physician should identify what the condition was and why it was an emergency (e.g., what could have happened to the patient if the treatment was delayed);
- o In the case of a pregnant woman, there was inadequate time to effect safe transfer to another hospital before delivery, or the transfer posed a threat to the health and safety of the woman or the unborn child;
- o The stabilizing treatment was appropriate (note that the clinical outcome of an individual's medical condition is not the basis for determining whether an appropriate screening was provided or whether the person transferred was stabilized);
- o The transfer was effected through qualified personnel and transportation equipment, including the use of medically appropriate life support measures;

- o The on-call physician's response time was reasonable; and

- o The transfer was appropriate for the individual.

Appropriate physician review may be performed by qualified SA physicians or under agreements or contracts with the State PRO, the State or local medical association, or other physician groups or individuals. If you have a physician available on the SA investigation team or in your office to perform the medical review, use the Physician Review Outline for Emergency Care Obligations of Medicare Hospitals (Exhibit 138) to communicate the results of the review. The specialty of the reviewing physician should be matched, if possible, to the specialty or specialties of the physician or physicians who treated the patient. Physician reviewers, as with any other type of investigator, must fully document their rationale for all decisions they render. Review physicians should be board-certified (if the physician being reviewed is board certified) and should be actively practicing in the same medical specialty as the physician treating the patient whose case led to an alleged violation.

If you recommend medical review of the case and you do not have a physician available in the SA to perform the review, indicate on Form HCFA-1541B that you recommend such review.

IX. TASK 7 - ASSESSMENT OF COMPLIANCE AND COMPLETION OF THE DEFICIENCY REPORT

A. Analysis.--Analyze your findings relative to each provision of the regulations for the frequency of occurrence, dates of occurrence, and patterns in terms of race, color, diagnosis, nationality, handicap, and financial status. A single violation is sufficient for an adverse recommendation. Older cases where the hospital implemented corrective actions with no repeat violations may require consultation with the RO concerning appropriate recommendations.

If the investigation was conducted by a team, the team should meet to discuss the findings. Consider information provided by the hospital. Ask the hospital for additional information or clarification about particular findings, if necessary.

Review each investigation tag number in this Appendix, and come to a consensus as to whether or not the hospital complies with each stated requirement. The following outline may be helpful in this review. For each requirement recommended as not met, record all salient findings on the HCFA-2567.

Outline of Data Tags Used For Citing Violations of
Responsibilities of Medicare Participating Hospitals in Emergency Cases

Deficiency Tags	Requirement
A400	Policies and Procedures Which Address Anti-Dumping Provisions
A401	Receiving Hospitals Must Report Suspected Incidences of Individuals With An Emergency Medical Condition Transferred in Violation of §489.24(d)

A402	Sign Posting
A403	Maintain Transfer Records for Five Years

	Seeking Emergency Services
A406	Appropriate Medical Screening
A407	Stabilizing Treatment
A408	No Delay in Examination or Treatment in Order to Inquire About Payment Status
A409	Appropriate Transfer
A410	Whistleblower Protections
A411	Recipient Hospital Responsibilities (Nondiscrimination)

B. Composing the Statement of Deficiencies (Form HCFA-2567).--Support all deficiency citations by documenting evidence obtained from your interviews and record reviews on Form HCFA-2567, Statement of Deficiencies and Plan of Correction. Deficiencies related to the Conditions of Participation should also be documented on Form HCFA-2567. Indicate whether your findings show that the deficiency constitutes an immediate and serious threat to patient health and safety (e.g., a situation that prevents individuals from getting medical screening examinations and/or a lack of treatment reflecting both the capacity and capability of the hospital's full resources, as guaranteed under §1867 of the Act.) Some examples include stabilizing treatment not provided; failure of an on-call physician to respond appropriately, improper transfer; or evidence that there was a denial of medical screening examinations and/or treatment to persons with emergency medical conditions as a direct result of requesting prior authorization from a managed care organization before medical assessment of the patient's condition). Examples of noncompliance which usually does not pose an immediate and serious threat include the following scenarios:

1. A transfer which was appropriate, but not signed or dated by the physician;

2. An approprate, functioning central log that on one particular day in not fully completed; and

3. A written hospital policy that is missing, but is nonetheless being implemented.

Do not make a medical judgment, but focus on the processes of the facility "beyond the paper." Identify whether single incidents of patient dumping which do not represent a hospital's customary practice, are nonetheless serious and capable of being repeated. Immediate and Serious violations require a 23-day termination track process. Non-immediate and serious violations require a 90-day track.

Write the deficiency statement in terms specific enough to allow a reasonably knowledgeable person to understand the aspect(s) of the requirement(s) that is (are) not met. Do not prescribe an acceptable remedy. Indicate the data prefix tag and regulatory citation, followed by a summary of the deficiency and supporting findings. When it is necessary to use specific examples, use patient identifier codes, not patient names.

The emergency services condition, or any other condition, is not automatically found out of compliance based on a violation of 42 CFR 489.20 and/or 42 CFR 489.24. A determination of noncompliance must be based on the regulatory requirements for the individual condition.

X. ADDITIONAL SURVEY REPORT DOCUMENTATION

Upon completion of each investigation, the team leader assures that the following additional documentation has been prepared for submission, along with Forms HCFA-1541B, HCFA-562, HCFA-2567, and a copy of the medical record (or records) to the HCFA RO:

A. Summary Listing of Sampled Cases and Description of Sample Selection. (See Task 2).--At a minimum, identify:

- The name of each patient chosen to be a part of the sample and the date of their request for emergency services;
- Any patient identifier codes used as a reference to protect the patient's confidentiality;
- The reason for including the patient in the sample (e.g., unstabilized transfer, lack of screening, lack of treatment, diagnosis, race, color, financial status, handicap, nationality); and
- Include a copy of the medical record(s) for all patients where the hospital violated the provisions in 42 CFR 489.24.

Also identify:

- How the sample was selected;
- The number of patients in the sample; and
- Any overall characteristics of the patients in the sample, such as race, color, nationality, handicap, financial status, and diagnosis.

B. Summary of Interviews. (See Task 4).--Identify how many interviews were conducted with patients, families, staff, physicians, administrators, managers, and others. At a minimum, include the individual's job title and/or assignment at the time of the incident, the relationship to the patient and/or reason for the interview, and a summary of the information obtained in each interview.

C. Complaint Investigation Narrative. (See Task 3).--Summarize significant findings in the medical records, meeting minutes, hospital policies and procedures, staffing schedules, quality assurance plans, hospital bylaws and regulations, training programs, credential files, personnel files, and contracted services reviewed in the course of the investigation. Briefly summarize your findings in the investigation and the rationale used for the course of action recommended to the RO.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A400	**§489.20 Basic Section 1866 commitments relevant to Section 1867 responsibilities.** The provider agrees-- (l) In the case of a hospital as defined in §489.24(b), to comply with §489.24.	INTERPRETIVE GUIDELINES: §489.20(l) §489.20(l) requires the provider to comply with §489.24. However §1866(a)(1)(l)(i) of the Act requires providers to adopt and enforce a policy to ensure compliance with the requirements of §1867 (§489.24). Non-compliance is a violation of the provider's agreement with the Health Care Financing Administration (HCFA). Therefore, if the provider violates §489.24, cite a corresponding violation of §489.20(l); but if the provider does not adopt and enforce procedures and policies to ensure compliance with §489.24, cite a violation of §1866(a)(1)(l)(i). o Check the bylaws/rules and regulations of the medical staff to determine if they reflect the requirements of §489.24 and the related requirements at §489.20. o Review the emergency department policies and procedure manuals for procedures related to the requirements of §489.24 and the related requirements at §489.20. The term "hospital" is defined in §489.24(b) as including a rural primary care hospital as defined in §1861(mm)(1) of the Act.
A401	(m) In the case of a hospital as defined in §489.24(b), to report to HCFA or the State survey agency any time it has reason to believe it may have received an individual who has been transferred in an unstable emergency medical condition from another hospital in violation of the requirements of §489.24(d).	INTERPRETIVE GUIDELINES: §489.20(m) Look for evidence that the receiving (recipient) hospital knew or suspected the individual had been to a hospital prior to the receiving (recipient) hospital and had not been transferred in accordance with §489.24(d). (Evidence may be obtained in the medical record or through interviews with the patient, family members or staff.) However, termination of the receiving (recipient) hospital should be suspended pending confirmation of the suspected offense. Review the emergency department log and medical records of patients received as transfers. Look for evidence that: o The hospital had agreed in advance to accept the transfers; o The hospital had received appropriate medical records; o All transfers had been effected through qualified personnel, transportation equipment and medically appropriate life support measures; and o The hospital had available space and qualified personnel to treat the patients.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A402	(q) In the case of a hospital as defined in §489.24(b)-- (1) To post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area) a sign (in a form specified by the Secretary) specifying the rights of individuals under section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor; and (2) To post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital participates in the Medicaid program under a State plan approved under Title XIX;	INTERPRETIVE GUIDELINES: §489.20(q) At a minimum: o The sign(s) must specify the rights of individuals with emergency conditions and women in labor who come to the emergency department for health care services; o It must indicate whether the facility participates in the Medicaid program; o The wording of the sign(s) must be clear and in simple terms and language that are understandable by the population served by the hospital; and o The sign(s) must be posted in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment (e.g., entrance, admitting area, waiting room, treatment area).
A403	(r) In the case of a hospital as defined in §489.24(b) (including both the transferring and receiving hospitals), to maintain-- (1) Medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of the transfer;	INTERPRETIVE GUIDELINES: §489.20(r)(1) The medical records of individuals transferred to or from the hospital must be retained in their original or legally-reproduced form in hard copy, microfilm, microfiche, optical disks, computer disks, or computer memory .

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A404	(2) A list of physicians who are on call for duty after the initial examination to provide further evaluation and/or treatment necessary to stabilize an individual with an emergency medical condition; and	INTERPRETIVE GUIDELINES: §489.20(r)(2) The purpose of the on-call list is to ensure that the emergency department is prospectively aware of which physicians, including specialists and subspecialists, are available to provide treatment necessary to stabilize individuals with emergency medical conditions. If a hospital offers a service to the public, the service should be available through on-call coverage of the emergency department. The medical staff by-laws or policies and procedures must define the responsibility of on-call physicians to respond, examine and treat patients with emergency medical conditions. Physicians, including specialists and subspecialists (e.g., neurologists) are not required to be on call at all times. The hospital must have policies and procedures to be followed when a particular specialty is not available or the on-call physician cannot respond because of situations beyond his or her control. Each hospital has the discretion to maintain the on-call list in a manner to best meet the needs of its patients. Physicians are not required to be on call in their specialty or subspecialty for emergencies whenever they are visiting their own patients in a hospital. Review the hospital's policy with respect to response time of the on-call physician. Hospitals are responsible for ensuring that on-call physicians respond within a reasonable period of time. Note the time of notification and the response (or transfer) time. If a staff physician is on-call to provide emergency services or to consult with an emergency room physician is in the area of his or her expertise, that physician would be considered to be available at the hospital. Where a physician is on-call in an office it is not acceptable to refer emergency cases to their offices for examination and treatment. The physician must come to the hospital to examine the patient unless the physician is a hospital-owned facility on contiguous land or on the hospital campus.. If a physician demonstrates a pattern of not arriving at the hospital while on-call, but directs the patient to be transferred to another hospital where that physician can treat the patient, this may be a violation.
A405	(3) A central log on each individual who "comes to the emergency department," as defined in §489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.	INTERPRETIVE GUIDELINES: §489.20(r)(3) The purpose of the central log is to track the care provided to each individual who comes to the hospital seeking care for an emergency medical condition. Each hospital has the discretion to maintain the central log in a form that best meets the needs of its patients. The central log includes, directly or by reference, patient logs from other areas of the hospital, such as pediatrics and labor and delivery where a patient might present for emergency services or receive a medical screening examination instead of in the emergency department. These additional logs must be available in a timely manner for surveyor review. Review the emergency department log covering at least a six month period that contains information on all patients coming to the emergency department and check for completeness, gaps in entries or missing information.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A405 (Cont.)		Select a sample of records from the past six months from the log for review to determine compliance with the §489.24 requirements, according to the sample size methodology in Task 2. Select an older sample if the case to be investigated occurred longer than six months ago, or if you are concerned about a possible long-term pattern of dumping.
	§489.24 Special responsibilities of Medicare hospitals in emergency cases.	**THE PROVISIONS OF THIS REGULATION APPLY TO ALL HOSPITALS THAT PARTICIPATE IN MEDICARE AND PROVIDE EMERGENCY SERVICES** Hospitals providing emergency services are required to provide for an appropriate medical screening examination; provide necessary stabilizing treatment for emergency medical conditions and labor; provide for an appropriate transfer of the patient if the hospital does not have the capability or capacity to provide the treatment necessary to stabilize the emergency medical condition; , not delay examination and/or treatment in order to inquire about the patient's insurance or payment status; accept appropriate transfers of patients with emergency medical conditions if the hospital has the specialized capabilities not available at the transferring hospital and has the capacity to treat those individuals; if the patient refuses examination, treatment, or transfer to obtain or attempt to obtain written and informed refusal of examination, treatment or appropriate transfer; and not take adverse action against a physician or qualified medical personnel who refuses to transfer a patient with an emergency medical condition, or against an employee who reports a violation of these requirements.
A406	(a) General. In the case of a hospital that has an emergency department,	INTERPRETIVE GUIDELINES: §489.24(a) A "hospital with an emergency department" is defined in paragraph (b) of this section as one which offers services for emergency medical conditions within its capability to do so. Lack of an established emergency department is not an indication that emergency services are not provided. If a hospital offers emergency services for medical, psychiatric or substance abuse emergency conditions, it is required, within its capability and capacity, to comply with all the anti-dumping statutory requirements. If a psychiatric hospital offers services for medical, psychiatric, or substance abuse emergency conditions, it is obligated to comply with all of the anti-dumping requirements of §§489.20 and 489.24. Most psychiatric hospitals are accredited by the Joint Commission and have an emergency department which provides reasonable care in determining whether an emergency exists, renders life saving first aid, and makes appropriate referrals to the nearest organizations that are capable of providing needed services. The emergency department must have a mechanism for providing physician coverage at all times.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A406 (Cont.)	If any individual (whether or not eligible for Medicare benefits and regardless of ability to pay) comes by him or herself or with another person to the emergency department and a request is made on the individual's behalf for examination or treatment of a medical condition by qualified medical personnel (as determined by the hospital in its rules and regulations), the hospital must provide for an appropriate MEDICAL SCREENING EXAMINATION within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department	Emergency services need not be provided in a location specifically identified as an emergency room or an emergency department. If an individual arrives at a hospital and is not technically in the emergency department, but is on the premises (including the parking lot, sidewalk and driveway) of the hospital and requests emergency care, he or she is entitled to a medical screening examination. For example, it may be the hospital's policy to direct all pregnant women to the labor and delivery area of the hospital. Hospitals may use areas to deliver emergency services which are also used for other inpatient or outpatient services. Medical screening examinations or stabilization may require ancillary services available only in areas or facilities of the hospital outside of the emergency department. As long as the patient is directed to a hospital-owned facility which is contiguous (i.e., any area within the hospital or a hospital-owned facility on land that touches land where a hospital's emergency department sits) or is part of the hospital "campus" and is owned by the hospital, and is operating under the hospital's provider number, the hospital is complying with §1867. Physicians' offices may be defined as such a facility, provided they are located in a hospital-owned building which is contiguous or located in a hospital-owned building which is"on campus." For example, a patient who presents to the emergency department could be sent to whatever hospital-owned contiguous or on-campus facility that the hospital deemed appropriate to conduct or complete the medical screening examination as long as (1)all persons with the same medical condition are moved to this location, regardless of their ability to pay for the treatment; (2)there is a bona fide medical reason to move the patient; and (3) qualified medical personnel accompany the patient. If the patient was initially screened in a facility outside of the emergency department, the patient could be moved to another hospital-owned contiguous or hospital-owned on-campus facility to receive additional screening or for stabilization without such movement being regarded as a transfer, as long as (1) all persons with the same medical condition are moved in such circumstances, regardless of their ability to pay for treatment; (2) there is a bona fide medical reason to move the patient; and (3) qualified medical personnel accompany the patient. If a patient comes to any contiguous or on-campus facility of a hospital that has one or more hospital-owned non-contiguous or off-campus facilities (such as an urgent care center or satellite clinic), the medical screening examination must be performed within the contiguous or on-campus facilities of the hospital. The hospital should not move the patient to a non-contiguous or off-campus facility for the medical screening examination.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A406 (Cont.)		If a patient comes to a hospital-owned facility which is non-contiguous or off-campus and operates under the hospital's Medicare provider number, §1867 applies to that facility. The facility must therefore screen and stabilize the patient to the best of its ability or execute an appropriate transfer according to §1867 guidelines if necessary. If an individual is not on hospital property, this regulation is not applicable. Hospital property includes ambulances owned and operated by the hospital, even if the ambulance is not on hospital grounds. An individual in a nonhospital-owned ambulance which is on hospital property is considered to have come to the hospital's emergency department. An individual in a nonhospital-owned ambulance not on "Hospital A's" property is not considered to have come to "Hospital A's" emergency department when the ambulance personnel contact "Hospital A" by telephone or telemetry communications. A hospital may deny access to patients when it is in "diversionary" status because it does not have the staff or facilities to accept any additional emergency patients at that time. However, if the ambulance disregards the hospital's instructions and brings the individual on to hospital grounds, the individual has come to the hospital and the hospital cannot deny the individual access to hospital services. Should a hospital which is not in diversionary status fail to accept a telephone or radio request for transfer or admission, the refusal could represent a violation of other Federal or State requirements (e.g., Hill-Burton). If you suspect a violation of related laws, refer the case to the responsible agency for investigation.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A406 (Cont)		Hospitals are obligated to screen patients to determine if an emergency medical condition exists. It is not appropriate to merely "log in" a patient and not provide a medical screening examination. Medicare participating hospitals that provide emergency services must provide a medical screening examination to any individual regardless of diagnosis (e.g., labor, AIDS), financial status (e.g., uninsured Medicaid), race, color, national origin (e.g., Hispanic or Native American surnames), handicap, etc. Individuals coming to the emergency department must be provided a medical screening examination beyond initial triaging. Triage is not equivalent to a medical screening examination. Triage merely determines the "order" in which patients will be seen, not the presence or absence of an emergency medical condition. A hospital, regardless of size or patient mix, must provide screening and stabilizing treatment within the scope of its abilities, as needed, to the individuals with emergency medical conditions who come to the hospital for examination and treatment. The medical screening examination must be the same medical screening examination that the hospital would perform on any individual coming to the hospital's emergency department with those signs and symptoms, regardless of the individual's ability to pay for medical care. If the medical screening examination is appropriate and does not reveal an emergency medical condition, the hospital has no further obligations under 42 CFR 489.24. Regardless of a positive or negative patient outcome, a hospital would be in violation of the anti-dumping statute if it fails to meet any of the medical screening requirements under 42 CFR 489.24. A medical screening examination is the process required to reach with reasonable clinical confidence, the point at which it can be determined whether a medical emergency does or does not exist. If a hospital applies in a nondiscriminatory manner (i.e., a different level of care must not exist based on payment status, race, national origin) a screening process that is reasonably calculated to determine whether an emergency medical condition exists, it has met its obligations under the Emergency Medical Treatment and Labor Act (EMTALA). Depending on the patient's presenting symptoms, the medical screening examination represents a spectrum ranging from a simple process involving only a brief history and physical examination to a complex process that also involves performing ancillary studies and procedures such as (but not limited to) lumbar punctures, clinical laboratory tests, CT scans, and/or diagnostic tests and procedures. A medical screening examination is not an isolated event. It is an ongoing process. The record must reflect continued monitoring according to the patient's needs and must continue until he/she is stabilized or appropriately transferred. There should be evidence of this evaluation prior to discharge or transfer.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A406 (Cont.)		The clinical outcome of an individual's condition is not a proper basis for determing whether an appropriate screening was provided or whether a person transferred was stabilized. However, it may be a "red flag" indicating a more thorough investigation is needed. Do not make decisions base on clinical information that was not available at the time of stabilization or transfer. If a misdiagnosis occurred, but the hospital utilized all of its resources, a violation of the screening requirement did not occur. A hospital may not refuse to screen an enrollee of a managed care plan because the plan refuses to authorize treatment or to pay for such screening and treatment. Likewise, the managed care plan cannot refuse to screen and treat or appropriately transfer individuals not enrolled in the plan who come to a plan hospital that participates in the Medicare program. It is not appropriate for a hospital to request or a health plan to require prior authorization before the patient has received a medical screening exam to determine the presence or absence of an emergency medical condition or until an existing emergency medical condition has been stabilized. Once an emergency medical condition has been determined not to exist or the emergency medical condition has been stabilized, §1867 of the Act no longer applies and prior authorization for further services can be sought. (NOTE: Background issue on Payment: Once a patient has presented to the hospital seeking emergency care, the determination of whether an emergency medical condition exists is made by the examining physician(s) or other qualified medical person actually caring for the patient at the treating facility, not the managed care plan. Beneficiaries have a right to emergency services if they have symptoms of sufficient severity (which may include severe pain) and sudden onset, and they are acting reasonably, given their knowledge, experiences, and state of mind.)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A406 (Cont.)		Prearranged community or State plans which identify certain hospitals that will care for selected individuals (e.g., Medicaid patients, psychiatric patients, pregnant women; (see tag A407)) do not relieve other hospitals of the obligation to comply with the screening and treatment requirements of §489.24 before appropriately transferring the individual. If a screening examination reveals an emergency medical condition and the individual is told to wait for treatment, but the individual leaves the hospital, the hospital did not "dump" the patient unless: o The individual left the emergency department based on a "suggestion" by the hospital, and/or o The individual's condition was emergent, but the hospital was operating beyond its capacity and did not attempt to transfer the individual to another facility. Hospital resources and staff available to inpatients at the hospital for emergency services must likewise be available to individuals coming to the hospital for examination and treatment of emergency medical conditions because these resources are within the capability of the hospital. For example, a woman in labor who presents at a hospital providing obstetrical services must be treated with the resources available, whether or not the hospital normally provides unassigned emergency obstetrical services. If a hospital chooses to meet its responsibility to provide adequate medical personnel to meet its anticipated emergency needs by using on-call physicians either to staff or to augment its emergency department, then the capability of its emergency department includes the services of its on-call physicians.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A406 (Cont.)	to determine whether or not an emergency medical condition exists.	"Emergency medical condition" means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbances, and/or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in: o Placing the health of the individual (or, with respect to a pregnant woman, the health of a woman or her unborn child) in serious jeopardy; o Serious impairment to any bodily functions; o Serious dysfunction of any bodily organ or part; or o With respect to a pregnant woman who is having contractions: -- That there is inadequate time to effect a safe transfer to another hospital before delivery, or -- That the transfer may pose a threat to the health or safety of the woman or the unborn child. Psychiatric hospitals that provide emergency services are obligated under these regulations to respond within the limits of their capabilities. Some intoxicated individuals may meet the definition of "emergency medical condition" because the absence of medical treatment may place their health in serious jeopardy, result in serious impairment of bodily functions, or serious dysfunction of a bodily organ. Further, it is not unusual for intoxicated individuals to have unrecognized trauma. Likewise, an individual expressing suicidal or homicidal thoughts or gestures, if determined dangerous to self or others, would be considered to have an emergency medical condition.
A406 (Cont.)	The examinations must be conducted by individuals determined qualified by hospital bylaws or rules and regulations and who meet the requirements of §482.55 concerning emergency services personnel and direction.	This delegation should be set forth in a document approved by the governing body of the hospital. If the rules and regulations of the hospital are approved by the board of trustees or other governing body, those personnel qualified to perform these examinations may be set forth in the rules and regulations, instead of placing this information in the hospital by-laws. It is not acceptable for the hospital to allow informal personnel appointments that could frequently change.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	(c) Necessary stabilizing treatment for emergency medical conditions and labor --	"Labor", as defined in paragraph (b) of this section, means the process of childbirth beginning with the latent or early phase of labor and continuing through the delivery of the placenta. A woman is in true labor unless a physician or qualified individual certifies that, after a reasonable time of observation, the woman is in false labor.
A407	(1) General. If any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition,	INTERPRETIVE GUIDELINES : §489.24(c)(I) A managed health care plan (e.g., HMO, PPO) cannot deny a hospital permission to treat its enrollees. It may only state what it will or will not pay for. Regardless of whether a hospital will be paid, it is obligated to provide the services specified in the statute and this regulation.
	the hospital must provide either--	
	(I) Within the capabilities of the staff and facilities available at the hospital,	Capabilities of a medical facility means that there is physical space, equipment, supplies, and services that the hospital provides (e.g., surgery, psychiatry, obstetrics, intensive care, pediatrics, trauma care). Capabilities of the staff of a facility means the level of care that the personnel of the hospital can provide within the training and scope of their professional licenses. The capacity to render care is not reflected simply by the number of persons occupying a specialized unit, the number of staff on duty, or the amount of equipment on the hospital's premises. Capacity includes whatever a hospital customarily does to accommodate patients in excess of its occupancy limits §489.24(b). If a hospital has customarily accommodated patients in excess of its occupancy limits by whatever means (e.g., moving patients to other units, calling in additional staff, borrowing equipment from other facilities) it has, in fact, demonstrated the ability to provide services to patients in excess of its occupancy limits. The by-laws, protocols and medical staff appointments approved by the governing body should require that all individuals are screened and stabilized within the capability of the hospital and should specify which staff members (by position) are authorized to perform the treatment. A hospital may appropriately transfer an individual before the sending hospital has used and exhausted all of its resources available if the individual requests the transfer to another hospital for his or her treatment, and refuses treatment at the sending hospital. (See Tag A409.) If a community-wide plan exists for certain hospitals to treat certain emergency medical conditions, then the individual should be screened, stabilized, or appropriately transferred to the community-plan hospital.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A407 (Cont.)	for Further Medical Examination and Treatment as required to stabilize the medical condition; or	Compliance with the medical screening examination and stabilization requirements under §1867 mandate that all patients with similar medical conditions be treated consistently. In some cases, local, State, or regionally-approved emergency medical systems (EMS), point-of-entry, and/or system protocols are in place. Compliance with EMS protocols with respect to the transport of emergent patients is usally deemed to indicate compliance with §1867; however a copy of the protocol should be obtained and reviewed at the time of the survey. If a hospital complies with other regional authority or State or locally approved point-of-entry protocols for emergency care (e.g., for psychiatric emergencies or physicial or sexual abuse) then the hospital is usually in compliance with §1867of the Act, as long as the hospital ensures that the patient is stable for transfer. If the individual seeking care is a member an HMO or CMP, the hospital's obligation to comply with the requirements of §489.24 is not affected. "To stabilize," as defined in paragraph (b) of this section means, with respect to an emergency medical condition, to either provide such medical treatment of the condition necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from, or occur during, the transfer of the individual from a facility, or that the woman has delivered the child and the placenta. A patient will be deemed stabilized if the treating physician attending to the patient in the emergency department/hospital has determined, within reasonable clinical confidence, that the emergency medical condition has been resolved. For patients whose emergency medical condition has not been resolved, the determination of whether they are stable "medically" may occur in one of the following two circumstances: o For purposes of transferring a patient from one facility to a second facility "stable for transfer"; and o For purposes of discharging a patient other than for the purpose of transfer from one facility to another facility "stable for discharge". For transfer between facilities: a patient is stable for transfer if the patient is transferred from one facility to a second facility and the treating physician attending to the patient has determined, within reasonable clinical confidence, that the patient is expected to leave the hospital and be received at the second facility, with no material deterioration in his/her medical condition; and the treating physician reasonably believes the receiving facility has the capability to manage the patient's medical condition and any reasonably foreseeable complication of that condition. If there is a disagreement between the treating physician and an off-site physician (e.g., a physician at the receiving facility or the patient's primary care physician if not physically present at the first facility)about whether a patient is stable for transfer, the medical judgment of the treating physician usually takes precedence over that of the off-site physician.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A407 (Cont.)	for **FURTHER MEDICAL EXAMINATION AND TREATMENT** as required to stabilize the medical condition; or	If a physician is not physically present at the time of transfer, then qualified personnel (as determined by hospital bylaws or other board-approved documents) in consultation with a physician can determine if a patient is stable for transfer. The failure of a receiving facility to provide the care it maintained it could provide to the patient when the transfer was arranged, should not be construed to mean the patient's condition worsened as a result of the transfer. A patient is considered stable for discharge (vs. for transfer from one facility to a second facility) when, within reasonable clinical confidence, it is determined that the patient has reached the point where his/her continued care, including diagnostic work-up and/or treatment, could be reasonable performed as an outpatient or later as an inpatient, provided the patient is given a plan for appropriate follow-up care with the discharge instructions. For purposes of transferring a patient from one facility to a second facility, for psychiatric conditions, the patient is considered to be stable when he/she is protected and prevented from injuring himself/herself or others. For purposes of discharging a patient (other than for the purpose of transfer from one facility to a second facility), for psychiatric conditions, the patient is considered to be stable when he/she is no longer considered to be a threat to him/herself or to others. "Stable for transfer" or "Stable for discharge" does not require the final resolution of the emergency medical condition. Hospitals may not circurnvent the requirements in §489.24 by admitting individuals with emergency medical conditions to other departments of the hospital and then discharging them prior to stabilization. These requirements apply to all areas of the hospital.
	(ii)For transfer of the individual to another medical facility in accordance with paragraph (d) of this section.	"Transfer" as defined in paragraph (b) of this section, means the movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual who has been declared dead or leaves the facility without the permission of any such person. If discharge would result in the reasonable medical probability of material deterioration of the patient, the emergency medical condition should not be considered to have been stabilized. When a hospital has exhausted all of its capabilities in attempting to remove the emergency medical condition, it must effect an appropriate transfer of the individual. (See Tag A409)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A407 (Cont.)	(2) Refusal to consent to treatment. A hospital meets the requirements of paragraph (c)(1)(i) of this section with respect to an individual if the hospital offers the individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual's behalf) refuses to consent to the examination and treatment. The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of a person acting in his or her behalf). The written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.	Emergency medical conditions must be stabilized. If a woman is in labor, the hospital must deliver the baby or transfer appropriately. She may not be transferred unless she, or a legally responsible person acting on her behalf, requests a transfer or if a physician or other qualified medical personnel, in consultation with a physician, certifies that the benefits to the condition of the woman and/or the unborn child outweigh the risks associated with the transfer. If the individual's condition requires immediate medical stabilizing treatment and the hospital is not able to attend to that individual because the emergency department is operating beyond its capacity, then the hospital should transfer the individual to a facility that has the capability and capacity to treat the individual's emergency medical condition, it possible. INTERPRETIVE GUIDELINES: §489.24(c)(2) The medical record should reflect that screening, further examination, and/or treatment was offered by the hospital prior to the individual's refusal. In the event an individual refuses to consent to further examination or treatment, the hospital must indicate in writing the risks/benefits of the examination and/or treatment; the reasons for refusal; a description of the examination or treatment that was refused; and the steps taken to try to secure the written, informed refusal if it was not secured. Hospitals may not attempt to coerce individuals into making judgments against their best interest by informing them that they will have to pay for their care if they remain, but that their care will be free or at low cost if they transfer to another hospital. A hospital cannot be left without recourse if an individual refuses treatment, refuses to sign a statement to that effect, and leaves against medical advice. Hospitals may document such refusals as they see fit. An individual may only refuse examination, treatment, or transfer on behalf of the patient if the patient is incapable of making an informed choice for him/herself.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A408	(3) Delay in examination or treatment. A participating hospital may not delay providing an appropriate medical screening examination required under paragraph (a) of this section or further medical examination and treatment required under paragraph (c) in order to inquire about the individual's method of payment or insurance status.	INTERPRETIVE GUIDELINES: §489.24(c)(3) Hospitals should not delay in providing a medical screening examination or necessary stabilizing treatment by inquiring about an individual's ability to pay for care. All individuals who have an emergency medical condition must be served, regardless of the answers the individual may give to the insurance questions asked during the registration process. In addition, a hospital may not delay screening or treatment to any individual while it verifies the information provided. However, hospitals may continue to follow reasonable registration processes for individuals presenting with an emergency medical condition. Reasonable registration processes may include requesting information about insurance as long as these procedures do not delay screening or treatment. If a delay in screening was due to an unusual internal crisis whereby it was simply not within the capability of the hospital to provide an appropriate screening examination at the time the individual came to the hospital (e.g., mass casualty occupying all the hospital's resources for a time period), interviews with staff members should elicit this information. This requirement applies equally to both the referring and the receiving (recipient) hospital.
A409	(d) Restricting transfer until the individual is stabilized.-- (1) General. If an individual at a hospital has an emergency medical condition that has not been stabilized (as defined in paragraph (b) of this section), the hospital may not transfer the individual unless-- (i) The transfer is an appropriate transfer (within the meaning of paragraph (d)(2) of this section); and	INTERPRETIVE GUIDELINES: §489.24(d)(1) (See the definition of "Stable for transfer" at Tag A407) INTERPRETIVE GUIDELINES: §489.24(d)(1)(i) There are 4 requirements of an "appropriate" transfer. These requirements are found in §§489.24(d)(2)(i), 489.24(d)(2)(ii), 489.24(d)(2)(iii), and 489.24(d)(2)(iv).

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A409 (Cont.)	(ii)(A) The individual (or a legally responsible person acting on the individual's behalf) requests the transfer after being informed of the hospital's obligations under this section and of the risk of transfer. The request must be in writing and indicate the reasons for the request as well as indicate that he or she is aware of the risks and benefits of the transfer;	INTERPRETIVE GUIDELINES: §489.24(d)(1)(ii)(A) The request must contain a brief statement of the hospital's obligations under the statute and the benefits and risks that were outlined to the person signing the request. Any transfer of an individual with an emergency medical condition must be initiated by either a written request for transfer or a physician's certification. If both are provided (as is often the case), the individual must still be informed of the risks vs. benefits of the transfer. The request must be made a part of the individual's medical record, and a copy of the request should be sent to the receiving (recipient) facility along with the individual transferred. If an individual's request for transfer is obtained by coercion or by misrepresenting the hospital's obligations to provide a medical screening examination and treatment for an emergency medical condition or labor, the request does not meet the hospital's obligations under these regulations.
A409 (Cont.)	(ii)(B) A physician (within the meaning of §1861(r)(1) of the Act) has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual or, in the case of a woman in labor, to the unborn child, from being transferred. The certification must contain a summary of the risks and benefits upon which it is based; or	INTERPRETIVE GUIDELINES: §489.24(d)(1)(ii)(B) Section 1861(r) of the Act defines physicians as: (i) A doctor of medicine or osteopathy. (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent recognized under State law or a State's regulatory mechanism); (ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license; (iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform; (iv) A doctor of optometry who is legally authorized to practice optometry by the State, but only with respect to services related to the condition of aphakia; or (v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by X-ray to exist.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A409 (Cont.)		The regulation requires an express written certification. Physician certification cannot simply be implied from the findings in the medical record and the fact that the patient was transferred. The certification must state the reason(s) for transfer. The narrative rationale need not be a lengthy discussion of the individual's medical condition reiterating facts already contained in the medical record, but it should give a complete picture of the benefits to be expected from appropriate care at the receiving (recipient) facility and the risks associated with the transfer, including the time away from an acute care setting necessary to effect the transfer. This rationale may be on the certification form or in the medical record. In cases where the individual's medical record does not include a certification, give the hospital the opportunity to retrieve the certification. Certifications may not be backdated. Document the hospital's response. Regardless of practices within a State, a woman in labor may be transferred only if she or her representative requests the transfer or if a physician or other qualified medical personnel signs a certification that the benefits outweigh the risks. If the hospital does not provide obstetrical services, the benefits of a transfer may outweigh the risks. A hospital cannot cite State law or practice as the basis for the transfer. Hospitals that are not capable of handling high-risk deliveries or high-risk infants often have written transfer agreements with facilities capable of handling high-risk cases. The hospital must still meet the screening, treatment, and transfer requirements. The certification that the benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the risk of the transfer is not required for transfers of individuals who no longer have an emergency medical condition. The date and time of the physician certification should closely match the date and time of the transfer.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A409 (Cont.)	(c) If a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as determined by the hospital in its by-laws or rules and regulations) has signed a certification described in paragraph (d)(1)(ii)(B) of this section after a physician (as defined in section 1861(r)(1) of the Act), in consultation with the qualified medical person, agrees with the certification and subsequently countersigns the certification. The certification must contain a summary of the risks and benefits upon which it is based. (d)(2) A **TRANSFER** to another medical facility will be **APPROPRIATE** only in those cases in which-- (i) The transferring hospital provides medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;	INTERPRETIVE GUIDELINES: §489.24(d)(1)(C) Individuals other than physicians may sign the certification of benefits versus risks of a transfer. These individuals must be identified in hospital bylaws, rules and regulations, or another board-approved document . If a certification of benefits versus risks was signed by a qualified medical person, a physician's countersignature must be present. Hospital by-laws or policies and procedures will describe the maximum amount of time allowed to obtain physician countersignatures on hospital documents. INTERPRETIVE GUIDELINES: §489.24(d)(2)(i) This is the first requirement of an appropriate transfer. The provision of treatment to minimize the risks of transfer is merely one of the 4 requirements of an appropriate transfer. If the patient requires treatment, it must be sufficient so that no material deterioration is likely to occur or result from the transfer. NOTE: The 4 requirements of an "appropriate" transfer are applied only if the transfer is to another medical facility. In other words, the hospital has the alternative of either (1) providing treatment to stabilize the emergency medical condition and subsequently discharging or transferring the individual, or (2) appropriately transferring an unstabilized individual to another medical facility if the emergency medical condition still exists. There is no "third" option of simply "referring" the individual away after performing step one (treatment to minimize the risk of transfer) of the 4 transfer requirements of an appropriate transfer.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A409 (Cont.)		If a patient is moved to another part of the hospital, the transfer requirements are not applicable because technically the patient has not been transferred. If an individual is moved to a diagnostic facility owned by another hospital with the intention of returning to the first hospital, an appropriate transfer (within the meaning of paragraph (d)(2) of this subsection) must still be effectuated. For example, when Hospital A shares a CT Scanner with Hospital B (Hospital B houses the CT Scanner), if Hospital A sends the individual to Hospital B for a CT scan as part of the appropriate medical screening examination to determine whether the individual has an emergency medical condition, the appropriate transfer requirements must be met. After the investigation of the transferring hospital, call or go to the receiving (recipient) facility and determine whether the receiving (recipient) facility verifies the transferring hospital's information. In cases of discrepancy, obtain the medical record from the transferring and receiving hospitals and the ambulance service for review. Review each hospital's information. If you determine that it is necessary to conduct a complaint investigation at the receiving (recipient) hospital, notify the RO to request an extension of the investigation timeframe. Review the transfer logs for the entire hospital, not merely the emergency department. Examine the following for appropriate transfers: o Transfers to off-site testing facilities and return; o Death or significant adverse outcomes; o Refusals of examination, treatment, or transfer; o Patients leaving against medical advise (AMA); o Returns to the emergency department within 48 hours; and o Emergency department visits where the patient is logged in for an unreasonable amount of time before the time indicated for commencement of the medical screening examination.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A409 (Cont.)	(ii) The receiving facility -- (A) Has available space and qualified personnel for the treatment of the individual; and (B) Has agreed to accept transfer of the individual and to provide appropriate medical treatment;	INTERPRETIVE GUIDELINES: §489.24(d)(2)(ii) This is the second requirement of an appropriate transfer. The transferring hospital must obtain permission from the receiving (recipient) hospital to transfer an individual. The transferring hospital should document its communication with the receiving (recipient) hospital, including the date and time of the transfer request and the name of the person accepting the transfer.
A409 (Cont.)	(iii) The transferring hospital sends to the receiving facility all medical records (or copies thereof) related to the emergency condition which the individual has presented that are available at the time of the transfer, including available history, records related to the individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) required under paragraph (d)(1)(ii) of this section, and the name and address of any on-call physician (described in paragraph (f) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment. Other records (e.g., test results not yet available or historical records not readily available from the hospital's files) must be sent as soon as practicable after transfer; and	INTERPRETIVE GUIDELINES: §489.24(d)(2)(iii) This is the third requirement of an appropriate transfer. Individuals being transferred to another hospital must be accompanied by necessary medical records. To the extent that services are performed before transfer, those services should be reflected in the medical records transferred. If transfer is in an individual's best interest, it should not be delayed until records are retrieved or test results come back from the laboratory. Whatever medical records are available at the time the individual is transferred should be sent to the receiving (recipient) hospital with the patient. Test results that become available after the individual is transferred should be telephoned to the receiving (recipient) hospital, and then mailed or sent via electronic transmission.
A409 (Cont.)	(iv) The transfer is effected through qualified personnel and transportation equipment, as required, including the use of necessary and medically appropriate life support measures during the transfer.	INTERPRETIVE GUIDELINES: §489.24(d)(2)(iv) This is the fourth requirement of an appropriate transfer. Emergency medical technicians may not always be "qualified personnel" for purposes of transferring an individual under these regulations. Depending on the individual's condition, there may be situations in which a physician's presence or some other specialist's presence might be mandatory. The physician at the sending hospital (and not the receiving hospital) has the responsibility to determine appropriate mode, equipment, and attendants for transfer.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A409 (Cont.)		While the hospital is ultimately responsible for ensuring that the transfer is effected appropriately, the hospital may meet its obligations as it sees fit. These regulations do not require that a hospital operate an emergency medical transportation service.
	(4) Refusal to consent to transfer. A hospital meets the requirements of paragraph (c)(1)(ii) of this section with respect to an individual if the hospital offers to transfer the individual to another medical facility in accordance with paragraph (d) of this section and informs the individual (or a person acting on his or her behalf) of the risks and benefits to the individual of the transfer, but the individual (or a person acting on the individual's behalf) refuses to consent to the transfer. The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of a person acting on his or her behalf). The written document must indicate the person has been informed of the risks and benefits of the transfer and the reasons for the individual's refusal. The medical record must contain a description of the proposed transfer that was refused by or on behalf of the individual.	INTERPRETIVE GUIDELINES: §489.24(c)(4) A hospital cannot be left without recourse if an individual or the individual's representative refuses transfer and also refuses to sign a statement to that effect. Hospitals may document such refusals as they see fit.
A410	(3) A participating hospital may not penalize or take adverse action against a physician or a qualified medical person described in paragraph (d)(1)(ii)(C) of this section because the physician or qualified medical person refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized, or against any hospital employee because the employee reports a violation of a requirement of this section.	INTERPRETIVE GUIDELINES: §489.24(d)(3) A "participating hospital" means a hospital that has entered into a provider agreement under §1866 of the Act.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
A411	(e) Recipient hospital responsibilities. A participating hospital that has specialized capabilities or facilities (including, but not limited to such facilities as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers) may not refuse to accept from a referring hospital within the boundaries of the United States, an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual.	INTERPRETIVE GUIDELINES: §489.24(e) Recipient hospitals only have to accept the patient if the patient requires the specialized capabilities of the hospital in accordance with this section. If the transferring hospital wants to transfer a patient because it has no beds or is overcrowded, but the patient does not require any "specialized" capabilities, the receiving (recipient) hospital is not obligated to accept the patient. If the patient required the specialized capabilities of the intended receiving (recipient) hospital, and the hospital had the capability and capacity to accept the transfer but refused, this requirement has been violated. Lateral transfers, that is, transfers between facilities of comparable resources, are not sanctioned by §489.24 because they would not offer enhanced care benefits to the patient except where there is a mechanical failure of equipment, no ICU beds available, or similar situations. However, if the sending hospital has the capability but not the capacity, the individual would most likely benefit from the transfer. The number of patients that may be occupying a specialized unit, the number of staff on duty, or the amount of equipment on the hospital's premises do not in and of themselves reflect the capacity of the hospital to care for additional patients. If a hospital generally has accommodated additional patients by whatever means (e.g., moving patients to other units, calling in additional staff, borrowing equipment from other facilities), it has demonstrated the ability to provide services to patients in excess of its occupancy limit. For example, a hospital may be able to care for one or more severe burn patients without opening up a "burn unit." In this example, if the hospital has the capacity, the hospital would have a duty to accept an appropriate transfer of an individual requiring the hospital's capabilities, provided the transferring hospital lacked the specialized services to treat the individual. The provisions of this requirement are applicable only when the sending hospital is located within the boundaries of the United States. Medicare participating hospitals with specialized capabilities or facilities are not obligated to accept transfers from hospitals located outside of the boundaries of the United States. RURAL REGIONAL REFERRAL CENTERS The criteria for classifying hospitals as rural regional referral centers have been defined in 42 CFR 412.96 for the purpose of exemptions and adjustments of payment amounts under the Prospective Payment System. The criteria in 42 CFR 412.96 are applicable to the nondiscrimination provisions of §489.24. Check with the Division of Medicaid and State Operations in the appropriate HCFA RO for information as to whether the hospital is designated as a rural regional referral center. A designated rural regional referral center is obligated to accept appropriate transfers of individuals who require the hospital's specialized capabilities if the hospital has the capacity to treat the individual.

APPENDIX W

SURVEY TASKS AND INTERPRETIVE GUIDELINES FOR CRITICAL ACCESS HOSPITALS (CAH)

I. EXPLANATION OF AUTHORITY AND DESCRIPTION

A. Statutory Citation.-- Section 4201 of the Balanced Budget Act of 1997, Public Law 105-33, amended §1820 of the Social Security Act by replacing the seven State Essential Access Community Hospital (EACH)/Rural Primary Care Hospital (RPCH) Program with a new Medicare Rural Hospital Flexibility Program. The new program is designed to promote rural health planning and network development, promote regionalization of rural health services in the State, and improve access to hospital and other health services for rural residents of the State. The Medicare Rural Hospital Flexibility Program will be available in any State which chooses to set up such a program and provides HCFA with the necessary assurances that it has developed, or is in the process of developing, a State rural health care plan meeting certain requirements, and that it has designated, or is in the process of designating, rural nonprofit hospitals or facilities as Critical Access Hospitals (CAHs).

B. Regulatory Citation.-- To allow the changes made by the enactment of Public Law 105-33 to be implemented by the statutory effective date of October 1, 1997, interim rules were published on August 29, 1997, at 62 **Federal Register** 45966. The regulatory approach was to retain the provisions of the existing RPCH regulations except where legislation clearly required HCFA to make a change. The Conditions of Participation for Critical Access Hospitals are found in 42 CFR Part 485, Subpart F.

C. Rural Health Network.-- A rural health network is an organization that meets the following specifications. It includes the following:

- At least one CAH; and
- At least one hospital that furnishes acute care services.

The network members have entered into agreements regarding the following:

- Patient referral and transfer;
- The development and use of communication systems; and
- The provisions of emergency and non-emergency transportation.

In addition, each CAH has an agreement with respect to credentialing and quality assurance with at least one hospital that is a member of the network, when applicable, or with a PRO or equivalent entity, or with another appropriate and qualified entity identified in the rural health care plan for the State.

D. Critical Access Hospital.-- A facility designated as a CAH by the State in which it is located which meets the following criteria:

- Is a rural public or nonprofit hospital located in a State that has established a Medicare Rural Hospital Flexibility Program;
- Is located more than a 35-mile drive from any other hospital or CAH (in mountainous terrain or in areas with only secondary roads available, the mileage criterion is 15 miles), or certified by the State as being a necessary provider of health care services to residents in the area;
- Makes available 24-hour emergency care services;
- Provides not more than 15 beds for acute (hospital-level) inpatient care;

NOTE: An exception to the 15-bed requirement is made for swing-bed facilities, which are allowed to have up to 25 inpatient beds that can be used interchangeably for acute or SNF-level care, provided that not more than 15 beds are used at any one time for acute care.

- Meets the same staffing requirements as those for the former RPCH program (see Part III-Interpretive Guidelines (Data Tags C250-C268)); and

o Keeps each inpatient for no longer than 96- hours, unless a longer period is required because of inclement weather or other emergency conditions, or a PRO or other equivalent entity, on request, waives the 96- hour time limit.

I. APPLICATION AND SUBMISSION OF A STATE RURAL HEALTH PLAN

A. Application.-- States who are interested in establishing a Medicare Rural Hospital Flexibility Program must submit an application to the Regional Administrator of the HCFA Regional Office responsible for oversight of Medicare and Medicaid in the State. This application may be submitted to the Regional Administrator through the Associate Regional Administrator. The application must be signed by an official of the State. The application will express the State's interest in developing a Medicare Rural Hospital Flexibility Program.

NOTE: There are no Federal forms and no set format for the application. However, the statute and regulations require that the State application will contain the following assurances:

o That the State has developed, or is in the process of developing, a State rural health care plan that provides for the creation of one or more rural health networks, promotes regionalization of rural health services in the State, and improves access to hospitals and other health services for rural residents of the State;

o That the State has developed the rural health care plan in consultation with the hospital association of the State, rural hospitals located in the State, and the State Office of Rural Health; and

o That the State has designated or is in the process of designating, rural nonprofit or public hospitals located in the State as Critical Access Hospitals.

B. Supportive Assurances.--The State must also provide other information in the application to support its assurances which include the following items as a minimum:

1. A copy of the State rural health care plan and a statement identifying the entity (e.g., State Office of Rural Health) responsible for implementing the plan;

2. In the case of a State that has completed work on its rural health care plan, letters or other documentation from the State Office of Rural Health (if that office is not primarily responsible for developing or implementing the plan), the State Hospital Association, and individual hospitals verifying that they were consulted during the development of the plan;

NOTE: If the State is in the process of developing the plan, the State should submit a copy of the current draft of the plan along with an anticipated completion date.

3. An explanation of how the State rural health plan will provide for the creation of one or more rural health networks, promote regionalization of rural health services, and improve access to hospitals and other health services for rural residents of the State;

4. A description of the process the State will follow to designate CAHs, including the method for identifying eligible facilities;

5. A listing of the facilities which the State has designated, or plans to designate, as Critical Access Hospitals; and

6. In the case of a State that has certified, or wishes to certify, that certain facilities are "necessary providers" of health care services in an area, a description of the criteria used to identify the facilities eligible for such certification.

III. RO REVIEW OF STATE ASSURANCE

A. Verification.-- The RO must verify that a State's application to establish a Medicare Rural Hospital Flexibility Program contains the necessary assurances to further the goal of the statute and regulations; that is, to assure access to essential health care services for rural residents. The statute and regulations give some discretion and flexibility, within a federal framework, for the State to designate CAHs.

The RO will review the copy of the State rural health care plan (or current draft). To approve a State's application, the RO verifies that the application contains assurances regarding:

1. The ability of the State's rural health care plan to create one or more rural health networks;

2. The ability of the State's rural health care plan to promote regionalization of rural health services in the State;

3. How the rural health care plan improves access to hospitals and other health services for rural residents in the State (e.g., the ability to get patients necessary hospital care, ability to link patients to physicians via telecommunications);

4. The development of the State's rural health care plan in consultation with the hospital association of the State, rural hospitals located in the State, and the State Office of Rural Health; and

5. How the State has designated, or is in the process of designating, rural nonprofit or public hospitals located in the State as Critical Access Hospitals (i.e., the methodology the State is using).

B. Supportive Information.-- In addition, the RO will verify that the following supportive information is present in the application:

1. A copy of the State's rural health care plan and a statement identifying the entity (e.g., the State Office of Rural Health) responsible for implementing the plan.

NOTE: Rural health care plans are developed based on some form of a community health assessment of the needs of the populations in the area. It is expected that each State that desires to create a Medicare Rural Hospital Flexibility Program would have its own rural health care plan meeting the needs of the State and that the rural health network(s) development would be dependent on local needs, resources, and willingness of various parties to enter into agreements. Therefore, the HCFA will expect to see differences from State to State regarding their rural health care plans. Differences in local needs and resources that might be reflected in the rural health care plan might include, for example:

- Access to primary care and emergency medical services
- Need for telemedicine services
- Upgrading of computer software to transfer patient care data
- Outreach services
- Emergency equipment
- Referral protocols for members of the network

2. An explanation of how the State rural health plan will provide for the creation of one or more rural health networks, promote regionalization of rural health services, and improve access to hospitals and other health services for rural residents of the State.

NOTE: In cases where the State has waived the 35-mile requirement in designating a CAH, the HCFA RO will verify that sufficient documentation is available which supports the State's position. That is, the State must show to the RO's satisfaction that the CAH is essential to the welfare of the community. If a RO believes the State has not adequately supported the State's designation of a CAH as a necessary provider, it should attempt to work with the State to obtain whatever additional information or rationale is needed to support the State's designation. If the issue cannot be resolved by these efforts, the RO should refer the issue to HCFA's central office for review and assistance.

3. A listing of the facilities which the State has designated, or plans to designate, as Critical Access Hospitals.

4. A description of how quality assurance and credentialing activities will be carried out. The statute and regulations state this may be done via the CAH having an agreement with a full service hospital in the network, via the appropriate PRO, or with another qualified entity as described in the rural health care plan.

5. A time frame for periodic review and evaluation of the plan by the State to assure that the plan is current and accomplishing what it is intended to accomplish.

C. Approval Notification.-- Section 1820(b)(3) of the Social Security Act authorizes HCFA to require other information and assurances in support of State rural health care plans. Therefore, HCFA will send the State a written request for any other information HCFA may need to complete a review of the application to establish a Medicare Rural Hospital Flexibility Program.

HCFA will review the application from the State for the assurances and other information listed above, and, where appropriate, will notify the State, in writing, that the State's application has been approved and CAH surveys may be conducted.

IV. MEDICARE PARTICIPATION BY A CAH--SA PROCEDURES.-- A CAH must be surveyed for compliance with the CoPs in 42 CFR Part 485, Subpart F, and if it has swing bed approval, for compliance with the specific CAH SNF requirements specified by 42 CFR 485.645(d).

A. CAH Applications.-- When a hospital that is both a new provider to Medicare and has been designated by the State as a CAH, contacts the SA to apply for Medicare participation as a CAH, the SA sends "Model Letter: Transmitting Materials to Critical Access Hospitals," (Exhibit 1) to the facility including copies of Form HCFA-1514, "Hospital Request for Certification in the Medicare/Medicaid Program" and Form HCFA-855, "Health Care Provider/Supplier Application." When the SA receives the completed Form HCFA-1514 and Form HCFA-855, the SA sends the completed forms to the designated intermediary for review and acceptance. Within 30 days, the intermediary will return the Form HCFA-1514 and Form HCFA-855 to the SA indicating if the application was approved or not approved. The State survey agency verifies that the facility has been properly designated as a CAH by the State government entity responsible for CAH designation prior to forwarding the application to the RO.

B. Arranging a CAH Survey.--After the RO has authorized a survey, the SA sends "Model Letter: Notification to Critical Access Hospitals Regarding Scheduling a Survey," (Exhibit 2) to the facility, including a copy of the Survey Tasks and Interpretive Guidelines for CAH (Appendix W). When arranging for and conducting the CAH survey, the SA follows the procedures outlined in "Part I--Sequence of Survey Tasks for Critical Access Hospitals." The SA contacts the administrator of the facility at least 2 weeks in advance to arrange for survey dates that are mutually acceptable to the SA and the facility. CAHs must have an agreement with at least one hospital that is a member of the network, or with a PRO or equivalent entity, with respect to credentialing and quality

assurance, or with another appropriate and qualified entity identified in the rural health care plan for the State. The SA advises the administrator that the individual(s) who is/are responsible for credentialing and quality assurance at the CAH must be available at some time during the survey to meet with the survey team.

C. Pre-survey Activity.-- The SA follows the procedures outlines in "Part I-- Sequence of Tasks for Critical Access Hospitals" and the procedure in "Task 1, Pre-Survey Preparation." The SA verifies requirements in the CAH CoPs in 42 CFR 485.608, 485.610, and 485.612 from facility files and other documentation available at its office. Also for a prospective CAH with swing-bed approval, the SA determines that the swing-bed approval is current. The law and regulations in effect before the effective date (August 5, 1997) of the Balanced Budget Act of 1997 provided specific rules relative to the number of beds that could be used to provide SNF-level care. For CAHs that were RPCHs, in such a situation, these facilities are allowed to continue under the same terms, conditions, and limitations as applied when their approvals were granted. (42 CFR 485.645(b))

D. Onsite Survey Activity.-- The SA follows the procedures in "Part 1," to include Task 2 through Task 8 when conducting its onsite survey at the CAH. The onsite portion of the survey will include all of the CoPs beginning with 42 CFR 485.616 through 485.645.

NOTE: Personnel qualifications for mid-level practitioners in a CAH, including clinical nurse specialists, nurse practitioners, and physician assistants, are described in 42 CFR 485.604. When reviewing CAH personnel files, refer to these requirements and applicable State licensure requirements in determining that CAH mid-level practitioners have the necessary training and experience.

E. Preparing Statement of Deficiencies.-- The SA uses the "Statement of Deficiencies and Plan of Correction," Form HCFA-2567, when citing deficiencies, and refers to the manual, "Principles of Documentation," for procedural guidance. The SA sends the completed Form HCFA-2567 and "Model Letter: Request for a Plan of Correction Following an Initial Survey" (Exhibit 3) to the facility.

V. RO PROCEDURES FOR CAH APPROVAL.-- A prospective CAH must be surveyed by the SA and be in compliance with the CoPs for CAHs in 42 CFR 485, Subpart F, before it can be approved for participation in Medicare as a CAH provider.

A. Verification Criteria.-- CAH verification requires that the RO review the facility file to determine if the prospective CAH is in compliance with the hospital CoPs in 42 CFR Part 482 at the time it made application for designation as a CAH. (See 42 CFR 485.612)

B. Notification.-- When the facility is found to be in full compliance with the CoPs in 42 CFR Part 485, Subpart F, or has submitted an acceptable Plan of Correction, the RO notifies the facility in writing by sending "Model Letter: CAH Approval Notification," (Exhibit 4), that it has been approved for participation. A copy of the notice letter is sent to the FI and SA. Do not issue the letter until the facility is in compliance with all the CoPs in 42 CFR Part 485, Subpart F.

C. Effective Dates.-- After the RO has reviewed and approved the SA recommendation for Medicare participation, the effective date for participation by a CAH will be one of the following:

- The last date of the initial survey by the SA, provided the prospective CAH is in full compliance with the CAH CoPs on that date; or
- The date that the prospective CAH submits an acceptable plan of correction to the SA.

I. GRAND FATHERING EXISTING FACILITIES.-- Under the Balanced Budget Act of 1997, no new Essential Access Community Hospital (EACH) designations will be made, but rural hospitals designated as EACHs under previous law will continue to be paid as sole community hospitals. The previous payment provisions applicable to RPCHs are repealed, and the law instead provides that CAHs will be paid on a reasonable cost basis for their services to inpatients and outpatients. The law provides that under certain conditions, existing RPCHs and Medical Assistance Facilities (MAFs) will be grand fathered as CAHs.

NOTE: Under a special provision applicable to the MAF program, the MAF demonstration project is extended until October 1, 1999, to allow for an appropriate transition between the MAF and CAH programs.

Previous law provided specific rules relating to the number of beds that a RPCH could use to provide SNF-level care. The new legislation provides considerable flexibility to use CAH inpatient beds for either SNF or acute care, as long as the total number of inpatient beds does not exceed 25 and the number of beds used at any one time for acute care does not exceed 15. However, some facilities which received approval from HCFA under previous law may wish to continue operating under the terms of that approval. To authorize this, the regulations will allow a CAH that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from HCFA to use its inpatient facilities to provide post-hospital SNF care, to continue in that status under the same terms, conditions, and limitations that were applicable at the time those approvals were granted. However, a CAH that was granted swing-bed approval under previous law may request that its application to be a CAH and a swing-bed provider be re-evaluated under current law and regulations. If this request is approved, the approval is effective not earlier than October 1, 1997, and the CAH may not request reinstatement under previously effective provisions.

VII. PROCEDURES FOR PROCESSING CAH SWING-BED APPLICATIONS.-- A CAH is eligible to participate in the Medicare hospital swing-bed program. A hospital that is not currently in the swing-bed program may apply to change its Medicare provider status to a swing-bed program without making a separate application to participate in the swing-bed program (i.e., as a new swing-bed provider). As a CAH with swing-beds, its overall bed count may not exceed 25, and at any one time, no more than 15 beds may be used for inpatient acute care. A facility that has been designated as a CAH by the State and certified as a CAH by HCFA may apply at any time to participate in the swing-bed program. Application is made using the "Request for Approval as a Hospital Provider of Extended Care Services (swing-bed) in the Medicare and Medicaid Programs," Form HCFA-605 (See Exhibit 81 of the State and Regional Operations Manual (SROM)). Only HCFA can approve an application to participate in the Medicare swing-bed program. When processing a CAH swing-bed application, the RO follows the procedures outlined in §§ 2036 through 2041.1 of the SROM.

VIII. RO PROCESSING COMPLAINTS AGAINST CAHS.-- When the RO or SA receives a complaint against a CAH regarding the CoPs in 42 CFR Part 485, Subpart F, including the SNF requirements for a swing-bed CAH, it follows the normal complaint process for non accredited hospitals in §§3280 and 3282 of the SOM.

IX. RO PROCESSING DENIALS OR TERMINATION FOR CAHS.--When the RO is processing denials or terminations for Medicare-participating hospitals that have been certified as CAHs, it follows the normal procedures that apply to Medicare-participating hospitals. For CAH terminations, the RO uses "Model Letter: CAH Denial Letter," (Exhibit 5).

X. CAH ANTI-DUMPING REQUIREMENTS -- Medicare participating hospitals must meet the requirements in §1867 of the Act, "Examination and Treatment for Emergency Medical Conditions and Women in Labor," and the applicable provisions of §1866 of the Act. The regulatory requirements are found in 42 CFR 489.24 and 489.20(l),(m),(q) and (r). For purposes of the anti-

dumping requirements the term "hospital" includes CAHs relative to these requirements (see 42 CFR 489.24(b)).

A. General Rule.-- The provisions of §1867 apply to all individuals (not just Medicare beneficiaries) who attempt to gain access to a hospital or a CAH for emergency care. The statute and regulation defines "hospital with an emergency department" to mean a hospital that offers services for emergency medical conditions within its capacity to do so.

The SA will investigate any alleged violation by a CAH according to the procedures found in §§3400 through 3413 of the SROM, "Conducting Investigations for Alleged Violations of 42 CFR 489.20(l),(m),(q) and (r) or 489.24, "Responsibilities of Medicare Hospitals in Emergency Cases."

B. Closed CAHs and 30-minute Rule.-- A CAH without inpatients is not required to have emergency staff on site 24 hours a day. However, 42 CFR 485.618(d) of the CAH CoPs requires a CAH to provide a practitioner, either a qualified mid-level practitioner (i.e., a physician assistant or nurse practitioner) or a physician (i.e., an M.D. or D.O.), on site within 30 minutes on a 24 hour- a day basis to treat emergency patients.

C. Patient Transfers And Anti-dumping Requirements.-- If a qualified medical person, in consultation with a physician, determines an appropriate transfer is necessary, the CAH must:

- Provide the medical treatment, within its capacity, which minimizes the risk of transfer to the patient;
- Send all pertinent medical records available at the time of transfer to the receiving hospital;
- Effect the transfer of the patient, through qualified personnel and transportation equipment, including necessary life support measures; and
- Obtain the consent of the receiving hospital.

The CAH may not transfer under the anti-dumping law unless the patient requests the transfer or the transfer is certified to be a medical necessity.

XI. ADVANCE DIRECTIVE REQUIREMENTS FOR CAHS.-- The requirements at 42 CFR 489.100, 489.102, and 489.104, apply advance directive requirements to CAH inpatients, including inpatients receiving SNF level of care in swing-beds. Therefore, when the SA is conducting a CAH survey, apply the advance directive requirement to all CAH inpatients. Refer to Data Tag No. C362 for guidance on surveying the advance directive requirement for CAH swing-bed patients.

MEDICARE RURAL HOSPITAL FLEXIBILITY PROGRAM

PART I
SEQUENCE OF SURVEY TASKS FOR CRITICAL ACCESS HOSPITALS (CAHS)

PART II--EXHIBITS

PART III
INTERPRETIVE GUIDELINES FOR CRITICAL ACCESS HOSPITALS

Column III Guidance to Surveyors
(Interpretive Guidelines and Additional Data Probes)

PART I: SEQUENCE OF SURVEY TASKS FOR CRITICAL ACCESS HOSPITALS

I. GENERAL INFORMATION.--A facility that participates in the Medicare program as a Critical Access Hospital (CAH) must meet the Medicare Conditions of Participation (CoPs) for CAHs at 42 CFR Part 485. Under the survey and certification procedures in 42 CFR Part 488, CAHs are included in the definition of "provider of services" and "provider" and therefore, CAHs are surveyed by the State Agencies (SA) and are subject to the same requirements as other providers.

The CAH Conditions of Participation (CoP) include the following:

" Compliance with Federal, State and local laws and regulations, 42 CFR 485.608;
o Status and Location, 42 CFR 485.610;
o Compliance with hospital requirements at time of application, 42 CFR 485.612;
o Agreements, 42 CFR 485.616;
o Emergency services, 42 CFR 485.618;
o Number of beds and length of stay, 42 CFR 485.620;
o Physical plant and environment, 42 CFR 485.623;
o Organizational structure, 42 CFR 485.627;
o Staffing and staff responsibilities, 42 CFR 485.631;
o Provision of services, 42 CFR 485.635;
o Clinical records, 42 CFR 485.638;
o Surgical Services, 42 CFR 485.639;
o Periodic evaluation and quality assurance review, 42 CFR 485.641; and
o Special requirements for CAH providers of long-term care services ("swing-beds"), 42 CFR 485.645.

II. PRINCIPLE FOCUS OF THE SURVEY

A. Intent of the Survey.--The intent of the CAH survey process is to evaluate facility compliance with each of the CoPs in the most efficient manner possible. Instead of proceeding condition-by-condition through the requirements, consider the interrelatedness of the regulations. Assess each CoP concurrently through observation, interviews with staff and patients, policy and procedures reviews and record reviews of open and closed patient records.

B. Focus of the Survey.--The principal focus of the survey is to evaluate the quality of care provided to patients at the CAH. In order to evaluate quality of care in the CAH, emphasize the following techniques:

1. Conduct direct observations and inspections, whenever possible, beginning with the facility tour (Task 3, recommended for all first-time certification surveys), and during your inspection of the facility (Task 5) when you will follow up your initial impressions and policy/procedures reviews with inspections of patient care areas and patient interviews;

2. Perform clinical reviews of patient records (Task 6) on a representative sample of records to determine the effectiveness of the CAH in treating inpatients and preparing inpatients for transfer as well as the quality of outpatient treatment provided at the CAH; and

3. Conduct interviews with CAH staff and CAH patients in the facility (Task 5) and, if needed, follow-up interviews with representatives of local 911 services, volunteer rescue services, etc., to determine the responsiveness of the CAH in meeting its emergency services requirements.

III. TASK 1 - PRE-SURVEY PREPARATION

A. Advance Notice.-- CAH surveys are announced in advance. Therefore, provide the facility administrator, director, or whomever is responsible for CAH operations with at least two weeks notice in order to arrange for a survey time that is mutually convenient for you and the facility. During your initial telephone contact with the CAH, inquire about such things as the expansion of services, current patient load and staff size, physical renovations at the facility, and significant changes in operations (e.g., revisions to the rural health network agreement, new services provided by arrangements or agreements, new transfer agreements with receiving hospitals). Before completing your initial telephone contact with the facility, offer to answer any questions about the CAH survey process and/or CAH requirements.

B. Planning the Survey.-- Determine the size of the survey team and the expected time required for the survey. The recommended survey team composition for a CAH survey is a three-member team composed of at least one registered nurse with hospital survey experience, one surveyor with experience in surveying rural health clinics (RHCs), and one Life Safety Code (LSC) specialist. If the CAH has a swing-bed approval, it is recommended that at least one member of the team have experience in surveying skilled nursing facilities (SNFs). Anticipate at least two days in the facility to complete the survey. Whenever possible, conduct surveys during routine hours of operation, (e.g., hours of operation of the CAH outpatient clinic).

C. Credentialing and Quality Assurance.-- During your initial telephone contact with the CAH, explain to the CAH representative that if the CAH intends to meet its quality assurance (QA) requirement at 42 CFR 485.641(b) through an arrangement (e.g., CAH QA is achieved through an arrangement with a hospital in the network), the individual who administers or directs the CAH QA program must be available to meet with the survey team at the CAH during the time the survey is conducted. That individual must also provide, or arrange to provide, QA documentation requested by the survey team. If possible, arrange a specific time when this individual can meet with the survey team member who will review QA. Also, inform the CAH representative in advance of the necessary QA documentation (e.g., QA policies and procedures, infection control logs, minutes of QA meetings) that will be needed to demonstrate compliance with 42 CFR 485.641(b).

D. Review the Facility File.-- Prior to each survey, review the facility's file, noting the facility's history of compliance/noncompliance, number and nature of deficiencies, plans of correction and existing waivers. Also review complaint allegations over the past year noting the frequency, significance, severity and, if substantiated, the resolution.

E. Pre-survey Research.-- Pre-survey preparation should include research to verify compliance with the following CoPs for CAHs:

1. Compliance with Federal, State, and local laws and regulations, (42 CFR 485.608) (C150 through C154).-- For facilities previously certified as CAHs under Medicare, review the facility file to determine that the facility is licensed in compliance with State law. Staff licensure, certification and/or registration (C154) will be reviewed on site, during the survey.

2. Status and Location, (42 CFR 485.610).-- (C160 through C162, C164) In initially designating a facility as a CAH, the State, or HCFA at 42 CFR 485.610(b)(3), has already determined that the facility is not located in a Metropolitan Statistical Area (MSA) or in an urban area. Prior to either an initial CAH survey or a resurvey, use geographical maps at the SA and/or Bureau of the Census publications listed in the Interpretive Guidelines for CAHs in Part III (C162 and C163) to confirm that the facility is not located in either an MSA or an urban area. To determine whether the facility has been classified by HCFA as an urban hospital, contact the Division of Medicare at the appropriate HCFA RO (refer to Data Tag C163 in Part III).

3. Compliance with hospital requirements at time of application, (42 CFR 485.612) (C170).--Before the initial CAH survey, review the facility file to make sure the facility has a Medicare hospital provider agreement. In the facility file, there should be evidence that the facility is in compliance with the Medicare hospital CoPs at the time the initial CAH survey is scheduled.

NOTE: Once a facility has been certified as a CAH by HCFA, it must qualify only under the CAH rules at 42 CFR Part 485, and not the hospital requirements.

4. Swing-Bed Approval, (42 CFR 485.645).--Determine if the CAH has a current swing-bed approval (C350). A facility that has been designated as a CAH by the State and certified as a CAH by HCFA may apply at any time to participate in the swing-bed program. CAHs with swing-bed approval must meet the applicable requirements (C350 through C405).

IV. TASK 2 - ENTRANCE CONFERENCE

A. The entrance conference sets the tone for the entire survey. Be prepared, courteous, and make requests, not demands. Upon arrival, present your identification, introduce the team members, reiterate to the facility's administrator, director, or supervisor the purpose of the survey, the time schedule previously agreed to, arrange for suitable work space for the survey team, and briefly explain the survey process.

B. Entrance Conference Activities.--

1. Verify application information (i.e., any variations in information on the application and actual facility operation), changes in current roster of personnel, changes in ownership and/or legal responsibility for day-to-day operations in the facility, changes in hours of operation;

2. Obtain the name of and verify the availability of key staff during the survey;

3. Confirm that the following documents will be available for review:

- o Facility policies and procedures covering all CAH requirements (i.e., infection control, pharmacy, emergency department, dietary, nursing, medical records, and outpatient /clinics);
- o List of services the facility provides directly and a list of services provided through arrangements or agreements;
- o Copy of all service agreements and any network agreements including participation in a communications system, physician coverage (if applicable), and referral, admission, and transportation of patients;
- o Organizational chart and position descriptions for all levels of personnel;
- o Staffing schedules for emergency department, outpatient/clinic department, nursing unit, etc., for the past three months;
- o On-call schedules for physicians, other staff (e.g. mid-level practitioners, laboratory, imaging, etc.), for the past three months;
- o Personnel files with evidence of appropriate licensure, certification, or registration, when applicable; (surveyors will request specific files during the survey)
- o Credential files for physicians and midlevel practitioners (surveyors will request specific files during the survey);
- o Committee meeting minutes for the past six months; (i.e., infection control, pharmacy and therapeutics, CAH policy development, quality assurance);
- o Governing body meeting minutes for the past six months;
- o Quality assurance plan;
- o Annual program evaluation;
- o Infection control log;

- Menus for one month for all diets offered;
- Incident reports for the past six months;
- List of authenticated signatures; and
- Current and closed medical records. (surveyors will request specific records during the survey).

V. TASK 3 - FACILITY TOUR

A. Purpose of Facility Tour.-- A brief facility tour by the survey team is expected, especially on initial certification surveys at hospitals that are converting to CAH providers, to help the survey team become familiar with the physical layout of the facility as well as the locations of key personnel. Even if surveyors are familiar with a facility from previous surveys, the facility may have undergone considerable physical renovations of its premises and made significant operating changes, including personnel changes, in order to downsize to a CAH. For example:

Physical renovations may often involve whole sections of the building being shut down and sealed off by physical partitions, relocation of departments to other parts of the building, changes to the physical plant, new equipment purchases and other similar changes that alter the manner in which the facility operates.

There may also have been major personnel changes, (e.g., the addition of mid-level practitioners, cutbacks in the number of physicians, registered nurses, and in auxiliary staff) that affect facility operations.

B. Initial Assessment.-- Another advantage of the facility tour is to give you the opportunity to make initial assessments relative to the cleanliness and infection control practices of the facility, the safety and emergency preparedness of the facility and staff, the appropriateness of patient treatment areas, and the ambiance of patient/staff interactions.

VI. TASK 4 - REVIEW OF POLICIES, PROCEDURES, AGREEMENTS OR ARRANGEMENTS

A. Required Policies, Procedures, Agreements or Arrangements.--A CAH must have policies, procedures, agreements or arrangements to comply with several of the CoPs for CAHs. In some instances, policies, procedures, agreements or arrangements must be in writing. In other instances the regulation requires the CAH to provide some evidence that a policy, procedure, agreement or arrangement is in effect. The following requirements (including the appropriate Data Tag Number from Part III) are included:

1. An agreement to participate in a network communications system if the CAH is in a network that participates in such a system (C190);

2. A policy or procedure, and if provided contractually, an agreement or arrangement, for services for the procurement, safekeeping and transfusion of blood, including the availability of blood products needed for emergency patients 24- hours -per- day (C205);

3. A procedure which demonstrates how the CAH, in coordination with local response systems, has a doctor of medicine or osteopathy immediately available by telephone or radio on a 24-hour-a-day basis to receive emergency calls, provide treatment information and refer patients to the CAH or to other appropriate locations for treatment (C209);

4. Evidence (e.g., minutes of board meetings of the governing body) which establishes that the CAH governing body or responsible individual assumes full responsibility for determining, implementing and monitoring all CAH policies governing CAH operations (C241);

5. Disclosure information showing the principal owners of the CAH (C242), the person principally responsible for CAH operations (C243), and the person responsible for medical direction in the CAH (C244);

6. Written policies and procedures that cover all health care services provided at the CAH (C271), including the following:

- o A description of the services furnished directly by the CAH and those services furnished through agreement and arrangement (C273);
- o Emergency medical services (C274);
- o Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, maintenance of health care records, and the periodic review and evaluation of the services furnished by the CAH (C275);
- o Rules for the storage, handling, dispensing, and administration of drugs and biologicals (C276);
- o Procedures for reporting adverse drug reactions and errors in the administration of drugs (C277);
- o A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel (C278);
- o Procedures that ensure that the nutritional needs of inpatients are met (C279);
- o A procedure for the annual review of policies by the professional staff described in 42 CFR 485.635(a)(2) (C280);

7. Emergency medical procedures as a first response to common life-threatening injuries and acute illness (C284);

8. Agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including the following:

- o Inpatient hospital care (C286);
- o Services of doctors of medicine or osteopathy (C287);
- o Additional or specialized diagnostic and clinical laboratory services not available at the CAH (C288); and
- o Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH (C289).
- o If agreements are not in writing, the CAH must be able to present evidence that patients referred by the CAH are being accepted and treated (C290).

9. A list of all services furnished under arrangements or agreements (C291);

10. Written policies and procedures for the maintenance of a clinical records system (C301);

11. Written policies and procedures governing the use and removal of records from the CAH and the conditions for release of information (C309);

12. Policies and procedures regarding who is allowed to perform surgery for CAH patients (C321);

13. Policies and procedures regarding who is allowed to administer anesthetics to CAH patients (C323);

14. Policies, procedures and/or other documentation that demonstrate that the CAH carries out the periodic evaluation of its total program as required in 42 CFR 485.641(a) (C330 through C335);

15. A quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished at the CAH (C336) which requires:

- o Evaluation of all patient care services and other services affecting patient health and safety (C337);
- o Evaluation of nosocomial infections and medication therapy (C338);
- o Evaluation of the quality and appropriateness of the diagnosis and treatment furnished by mid-level practitioners at the CAH by a doctor of medicine or osteopathy who is a member of the CAH staff or under consult with the CAH (C339).
- o An agreement for the evaluation of the quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH with at least one hospital that is a member of the network , the Peer Review Organization (PRO) for the State in which the CAH is located, or equivalent entity, or with another appropriate and qualified entity defined in the State rural health care plan (C340);
- o Evaluation of the reviewing entity's findings and recommendations along with corrective action by the CAH (C341);
- o Procedures to take remedial action to address deficiencies found through the quality assurance program (C342); and
- o Documentation of the outcomes of any remedial actions taken (C343).

NOTE: If QA at the CAH is obtained by arrangement with a hospital, determine what channels of communication have been established between the contractor and facility staff. Also, if QA is obtained through an arrangement, determine if the program has the following: an ongoing data collection system, a problem identification and data analysis system, and a system to identify, implement and evaluate any corrective actions that are taken.

B. Additional Optional Written Documentation.-- There are other sections in the CAH CoPs that do not specifically require written policies and procedures. However, the facility may choose to develop written policies and/or procedures for some or all of these requirements, including the following:

1. Ensuring that supplies, drugs and biologicals are periodically ordered and monitored (C203 and C204);

2. Written policies and/or procedures requiring the discharge or transfer of patients within 96 hours of admission (C212);

3. Written policies and procedures ensuring that sufficient staff are available to provide essential services for CAH operation (C253);

4. Delineating specific CAH responsibilities for the doctor of medicine or osteopathy (C256 through C260), and for mid-level practitioners (C262 through C265);

5. Ensuring that all written policies pertaining to health care services furnished in the CAH are developed with the advice of one or more doctors of medicine or osteopathy and one or more mid-level practitioners, if they are on staff, at least one of whom is not a member of the CAH staff (C272);

6. Ensuring that the person responsible for CAH operations is also responsible for contracted services (C292) and that those contracted services, including contracts for shared services and joint ventures, are provided in a manner that allows the CAH to comply with the CoPs for CAHs (C293);

7. Ensuring that a registered nurse (RN) provides or assigns to other personnel the nursing care for each patient (C295), and that an RN, or if applicable, a physician assistant, supervises and evaluates the nursing care for each patient (C296); and

8. Ensuring that the confidentiality of medical records is maintained and that records are protected against loss, destruction or unauthorized use (C308), and are retained for at least six years (C311).

C. Sampling Techniques.--These pre-selection procedures (i.e., inpatient and outpatient records) are not to be used for first-time certification surveys (see first paragraph under Task 6).

Before you begin Task 5 (Facility Inspection/Interviews With Staff), a member of the survey team should request from the medical records staff person who was identified during the Entrance Conference, the emergency services log, the outpatient treatment log, a list of current admissions and discharges to select an appropriate sample of patient medical records. Since the CAH survey is an announced survey, it is important that the sample of medical records be selected by the survey team, and not by the facility.

Select a sample of outpatient medical records from both the emergency services log and the outpatient clinic log. Since CAHs must meet all of the §1867 anti-dumping requirements, try to include in your sample emergency services records for patients who left the CAH against medical advice and/or were transferred.

For surveys conducted after the initial survey, the size of the medical records sample should be at least 10% of the annual census but not more than 30 records. Select a sample of current and inpatient discharge records for review.

Before you begin Task 5 (below), make arrangements to have these outpatient and inpatient records made available for examination when you begin Task 6.

VII. TASK 5 - FACILITY INSPECTION/INTERVIEWS WITH STAFF

A. Planning the Facility Inspection.-- Taking into account such things as the physical layout of the CAH, the number and scope of services offered, the availability of key staff, and your impressions of the CAH based on the facility tour and your review of written documents, you should begin a physical inspection of the facility, including interviews with staff, as needed.

B. Inspection Sites.-- At a minimum, inspect the following areas:

1. Emergency services (C201 through C209).-- Through inspections and interviews with emergency services staff, ascertain the following: the methodology used by the CAH to make emergency services available 24- hours-a-day; the availability and condition of equipment, supplies, drugs and biologicals; the availability of blood and blood products; the methodology used to meet the 24-hour availability and 30 minute on-call requirements; and the methodology used to link the CAH with local emergency response systems;

2. Physical plant and environment (C220 through C233).-- Reviewed as part of the Life Safety Code inspection;

3. Drug storage area (C276).-- Through inspections and interviews with staff, ascertain how drug storage is managed, how records are kept, and how all outdated, mislabeled, or otherwise unusable drugs are made unavailable for patient use;

4. Direct care services (C281).-- Through inspections and staff interviews ascertain how the CAH is providing diagnostic and therapeutic services for patients;

5. Laboratory services (C282).-- Through inspection and interviews with staff, ascertain that the CAH has an appropriate CLIA certificate and that the CAH has the capability (i.e., proper equipment and records) to perform all required laboratory tests listed in 42 CFR 485.635(b)(2);

6. Radiology services (C283).-- Through inspections and interviews with staff, ascertain that the CAH radiology staff are properly qualified and that radiology services are provided in a manner that is safe for patients and staff;

7. Inpatient treatment areas.-- Through inspections and interviews with staff, ascertain that the CAH has an inpatient treatment area with no more than 15 beds (C211) or no more than 25 beds (if it has a swing-bed agreement (C351)), the CAH has adequate numbers of qualified professional and ancillary staff to care for its inpatients (C250 through C255), there is a methodology to assure that nursing care for each patient is supervised and evaluated by a registered nurse, and there is a current nursing care plan for each inpatient (C294 through C298);

8. Clinical records (C300 through C303).-- Through inspections and interviews with staff, ascertain that the CAH has an effective clinical records system maintained in accordance with its written policies and procedures, records are systematically organized, and a designated member of the professional staff is responsible for the records area; and

9. Swing-beds (C350 through C405).-- Through inspections and interviews with staff, determine if the CAH is in compliance with all of the SNF requirements listed in section 42 CFR 485.645.

VIII. TASK 6 - MEDICAL RECORDS REVIEW

A. Initial/Re-survey.-- For a first-time CAH survey (i.e., a hospital applying for its initial Medicare CAH certification), the records review will consist of the review of medical records policies and procedures described in Task 4, and the inspection of the medical records area in Task 5. The procedure described below is to be used only for resurveys (i.e., surveys conducted after the first time certification survey). Address the following CAH requirements, as appropriate for each record, in the course of your medical records review:

1. Emergency treatment is provided by qualified staff in a timely manner (C207 and C208);

2. Physician consultation is available if such consultation is necessary to treat the emergency services patient (C209);

3. Records for patients treated by CAH mid-level practitioners (inpatient and outpatient sample) are reviewed and signed by a doctor of medicine or osteopathy (C259 and C260);

4. Mid-level practitioners arrange for or refer their patients (inpatient and outpatient sample) to needed services not furnished at the CAH (C267);

5. A doctor of medicine or osteopathy is notified timely of all inpatient admissions by mid-level practitioners in the CAH (C268);

6. Patients (whether inpatient or outpatient) receive health care services consistent with written policies for the CAH (C271);

7. The CAH seeks medical consultation and/or refers patients (inpatient and outpatient sample) in a manner consistent with its guidelines for consultation and/or referral (C275); and

8. Inpatients' nutritional needs are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of patients (C279).

B. Contents of Patient Record.--

1. Identification and social data, properly executed informed consent forms, medical history, health care status and needs assessment, and a summary of the episode, disposition and instructions to the patient (C304);

2. Reports of physical examinations, diagnostic and laboratory test results and consultative findings (C305);

3. All orders of physicians and/or mid-level practitioners, reports of treatment or medications, nursing notes, documentation of complications, and other pertinent information necessary to monitor patient progress (C306);

4. Dated signatures of the doctor of medicine or osteopathy or other health care professional (C307); and

5. Patient consent forms, if applicable, for the release of any records information not required by law (C310).

IX. TASK 7 - ANALYSIS AND EVALUATION OF FINDINGS

A. Preliminary Discussion.-- If the survey was performed by a team, the team should meet to discuss the findings. Consider information provided by the CAH, and ask the CAH for additional information or clarification about particular findings, if necessary. Wait to make an evaluation of whether a finding constitutes a deficiency and whether a Condition-level deficiency exists until after all necessary information is collected. Review the findings from each task and decide whether further information and/or documentation is necessary. Include in your analysis an evaluation of additional information provided by the CAH.

B. Immediate and Serious Threat.-- In situations where you believe that there may be an immediate and serious threat of harm or injury to CAH patients, make your determination in accordance with the procedures outlined in Appendix Q. If you determine that an immediate and serious threat exists, follow the termination procedures in §3010. If you identify an immediate and serious threat on a first-time CAH certification survey (i.e., a facility that has not yet been certified as an CAH, but is certified as a hospital under Medicare), follow the procedures in §3010 relative to the prospective CAH's hospital provider agreement.

C. Staff and Individual Allegations.--Handle all staff or individual allegations of deficiencies (i.e., allegations that may involve Condition-level deficiencies) as complaints, and determine, as much as possible, the validity of the allegations prior to leaving the CAH. Do not cite health and safety issues considered deficient by individuals or staff without verification. Conduct a follow-up survey, if appropriate, of serious allegations.

D. Analysis of Findings.-- When the survey team has determined that sufficient evidence exists to develop findings, analyze these findings relative to each requirement for degree of severity, frequency of occurrence, and the impact on care provided to patients. The number of deficiencies does not necessarily relate to whether or not a CoP should be found out of compliance, but rather its impact or potential impact on the health and safety of patients.

X. TASK 8 - EXIT CONFERENCE.--

The purpose of the exit conference is to inform the CAH staff of your observations and findings and to provide an opportunity for the CAH to present additional information in response to the surveyor's findings.

Conduct the Exit Conference with the CAH administrator, director, supervisor, and other invited staff, and address the following:

- The CAH requirements that are not in compliance and the findings that substantiate these deficiencies. Describe other observations or findings that may result in a deficiency;
- Any request from the CAH to discuss and provide additional information. Attempt to resolve differences regarding deficiencies, and explain that it is the CAH's responsibility to determine the corrective action(s) necessary to remedy the problem(s);
- Your intended recommendation to the RO to certify, recertify or deny certification of the CAH; subject to review by the State agency supervisor; and
- If necessary, instructions and the time frame necessary for submitting a plan of correction.

XI. TASK 9 - DEVELOPMENT OF STATEMENT OF DEFICIENCIES.--

Write the deficiency statement in terms specific enough to allow a reasonably knowledgable person to understand the aspects of the requirements that are not met. It is not always possible, or necessary, to determine the cause of the deficiency. Do not delve into the CAH's policies and procedures or sift through various alternative to prescribe an acceptable remedy.

Document deficiencies on the Form HCFA-2567, Statement of Deficiencies and Plan of Correction, and refer to the manual, "Principles of Documentation" for detailed instructions on the documentation of citations. As necessary, discuss survey findings with more experienced surveyors in the SA or RO.

Part II: Exhibit 1
Model Letter: Letter Transmitting Materials to Critical Access Hospital (CAH)

Name/Title of CAH Administrator, CEO, or Responsible Individual
Name of CAH
Street Address
City, State, Zip Code

Dear _____:

This letter concerns the requirements and procedures through which (name of facility) may be approved under Medicare as a Critical Access Hospital (CAH). This State survey agency (SA) certifies and periodically recertifies CAHs to assist the Health Care Financing Administration (HCFA) in determining whether they meet the Medicare Conditions of Participation for CAHs at 42 Code of Federal Regulations (CFR), Part 485. Such approval is a prerequisite to qualify for participation in the Medicaid program as well.

To be eligible for certification under Medicare as a CAH, (name of facility) must first be designated as a CAH by the State in which you are located, provided that the State also has established a Medicare Rural Hospital Flexibility Program (MRHFP). In addition, it must also:

- Be a rural public or nonprofit hospital located in a State that has established a MRHFP;

- Have a Medicare participation agreement as a hospital and be in compliance with the Medicare hospital Conditions of Participation (CoPs);

- Be located more than a 35 mile drive from any other hospital or CAH (in mountainous terrain or in areas with only secondary roads available, the mileage criterion is 15 miles); or certified by the state as a necessary provider of health care services to residents in the area;

- Agree to make available 24-hour emergency services;

- Provide not more than 15 beds for acute (hospital-level) inpatient care;

NOTE: An exception to the 15-bed requirement is made for swing-bed facilities, which are allowed to have up to 25 inpatient beds that can be used interchangeably for acute or SNF-level care, provided that not more than 15 beds are used at any one time for acute care.

- Agree to keep each inpatient for no longer than 96 hours, unless a longer period is required because of inclement weather or other emergency condition or a PRO, or other equivalent entity, on request, waives the 96 hour restriction; and

- Meet the requirements of the CoPs for CAHs found at 42 CFR Part 485 (copy enclosed).

The enclosed application forms, "Hospital Request for Certification in the Medicare/Medicaid Program" (Form HCFA-1514) and the "Medicare Health Care Provider/Supplier Enrollment Application" (Form HCFA-855), must be completed, signed and returned to the State agency to be forwarded to the intermediary for review if the facility wishes to be approved.

After your facility's eligibility has been decided, we will arrange to perform a survey to determine compliance with the CAH CoPs. Our surveyors will inspect the facility, interview you and members of your staff, review documents, and undertake other procedures necessary to evaluate the extent to which the facility meets the CAH CoPs. If the facility has significant deficiencies in any of the CAH CoPs, you will be informed and given an opportunity to correct them.

Please be advised that (name of facility) may not be paid as a CAH prior to the effective date for certification in the Medicare program.

Please do not hesitate to contact this office at (telephone number of SA) if you have any questions regarding the CAH survey process.

Sincerely,

(State Agency)

Enclosures: 42 C.F..R Part 485, Subpart F
Hospital Request for Certification in the Medicare/Medicaid Program (Form HCFA- 1514)
Medicare Health Care Provider/Supplier Enrollment Application (Form HCFA-855)

cc:
HCFA Regional Office

Part II: Exhibit 2
Model Letter: Notification to Critical Access Hospital (CAH)
Regarding Scheduling a Survey

Name/Title of CAH Administrator, CEO, or Responsible Individual
Name of CAH
Street Address
City, State, Zip Code

Dear _____:

The purpose of this letter is to notify you that (name of CAH) has been scheduled for a health and safety survey for compliance with the Conditions of Participation at 42 CFR Part 485, Subpart F on (Date of Survey).

Please make available for review at the time of the survey the following materials:

- o Facility policies and procedures covering all CAH requirements; (e.g., infection control, pharmacy, emergency department, dietary, nursing, medical records, outpatient/clinics);

- o List of services the facility provides directly and a list of services provided through arrangements or agreements;

- o Copy of all service agreements and any network agreements including participation in a communications system, physician coverage (if applicable), and referral, admission, and transportation of patients;

- o Organizational chart and position descriptions for all levels of personnel;

- o Staffing schedules for emergency department, outpatient/clinic department, nursing unit, etc., for the past three months;

- o On-call schedules for physicians, other staff, e.g. mid-level practitioners, laboratory, imaging, etc., for the past three months;

- o Personnel files with evidence of appropriate licensure, certification, or registration, when applicable; (surveyors will request specific files during the survey)

- o Credentials files for physicians and mid-level practitioners; (surveyors will request specific files during the survey)

- o Committee meeting minutes for the past six months; (e. g., infection control, pharmacy and therapeutics, CAH policy development, quality assurance)

- o Governing body meeting minutes for the past six months;

- o Quality assurance plan;

- o Annual program evaluation

- o Infection control log;

- o Menus for one month for all diets offered;
- o Incident reports for the past six months;
- o List of authenticated signatures; and
- o Current and closed medical records. (surveyors will request specific records during the survey)

NOTE: If QA requirements at 42 CFR 485.641(b) are provided by arrangement with a Medicare-participating hospital, PRO, or other equivalent entity, the individual responsible for the CAH QA program must be available to meet with the survey team. That individual must also make available documentation needed by the survey team to conduct an evaluation of the facility's QA program.

Within 5 days of receipt of this letter notify (Contact Person) at the State agency in writing of the CAH hours of operation and the type of mid-level practitioners employed at the facility.

Should you need additional information about the survey, do not hesitate to call us. In the event that it is not possible for the facility to participate in a survey on the date scheduled, please call (Name and telephone number) at (State agency location).

Sincerely,

(State Agency)

Enclosure: Appendix W, "Survey Tasks and Interpretive Guidelines"

Part II: Exhibit 3
Model Letter: Request for a Plan of Correction
Following an Initial Survey

Name/Title of CAH Administrator, CEO, or Responsible Individual
Name of CAH
Street Address
City, State, Zip Code

Dear_____:

You will find enclosed the Form HCFA-2567 "Statement of Deficiencies and Plan of Correction," which enumerates deficiencies found as a result of the initial Medicare certification survey completed at your facility on (date).

Although a reasonable period of time may be allowed for actual correction of these deficiencies, your plan of correction must be returned to this office signed and dated with an anticipated completion date for each corrective action, within ten (10) days of receipt of this letter.

The plan of correction will be reviewed at the State agency upon receipt and, if found to be acceptable, a recommendation for participation in the Medicare program will be made to the HCFA regional office. The effective date of certification will be the date that an approved plan of correction for the facility was received at the State agency.

A complete copy of the Form HCFA-2567 is subject to public disclosure. All responses must be shown on this form. Attachments may be submitted as supporting documentation. **NOTE: "CORRECTED" is not an acceptable reply.** Please be specific as to how the deficient practice will be or has been corrected. Failure to do so will result in the plan being returned for revision creating a delay in the approval of your plan of correction.

Your plan of correction must contain the following:

- What measures will be put into place or what systematic changes will you make to ensure that the deficient practice does not recur; and
- How will the corrective action(s) be monitored to ensure compliance. (e.g., What quality assurance indicators will be put into place?)

Sincerely,

(State Agency)

Enclosure: Form HCFA-2567

MEDICARE RURAL HOSPITAL FLEXIBILITY PROGRAM

Part II: Exhibit 4
Model Letter: CAH Approval Notification

Name/Title of CAH Administrator, CEO, or Responsible Individual
Name of CAH
Street Address
City, State, Zip Code

Dear _____:

We are pleased to notify you that (name of CAH) meets the requirements at 42 Code of Federal Regulations (CFR), Part 485, for participation in the Medicare program as a critical access hospital (CAH). The effective date of this approval is (effective date).

Effective with the approval of (name of CAH) as a CAH, its participation as an acute care hospital under provider number (hospital provider number) has been canceled, effective (date before CAH effective date). Your new provider number for CAH status is (CAH provider number). Your CAH provider number should be used on all correspondence and billing for the Medicare program.

(Insert next two paragraphs if necessary):

(Name of CAH) has been furnished a "Statement of Deficiencies and Plan of Correction" (Form HCFA-2567). The deficiencies on that form reflect the evaluation of your compliance with the Conditions of Participation for CAHs. Under "Provider Plan of Correction" on the right-hand side of this form (name of CAH) has listed its response to each deficiency. A complete copy of that form is subject to public disclosure.

The State survey agency (SA) will continue to work with (name of CAH) on its correction plan. The SA will complete a "Post-Certification Revisit Report" (Form HCFA-2567B) documenting the corrections (name of CAH) has made. If (name of CAH) has not corrected all deficiencies, it will be asked to explain why they have not been corrected and a new Plan of Correction must be submitted.

(Insert next paragraph if necessary):

(Name of CAH) has also been approved to provide post-hospital skilled nursing facility care as specified in 42 CFR Part 409.30. Swing-bed CAHs are assigned an additional number which contains an alpha-character in the third position. The third character, the letter "Z", indicates that the CAH has been approved as a swing-bed CAH. Therefore, the swing-bed identification number for (name of CAH) will be (swing-bed provider number).

The change in status of (name of CAH) will require that limited services begin no later than (CAH effective date). You may operate no more than 25 beds (with no more than 15 used for acute inpatient care at any one time with a maximum stay of 96 hours). All billing for patient services through (last date before effective date), should be billed under provider number (hospital provider number). All services furnished on or after

(CAH effective date), should be billed under provider number (CAH provider number).

Your fiscal intermediary continues to be (or "will be", as appropriate) (name of fiscal intermediary). Billings for services should be made under (CAH provider number). (Insert next sentence if necessary:) The "Z" number is to be used for all billings for services for Title XVIII SNF services.

MEDICARE RURAL HOSPITAL FLEXIBILITY PROGRAM

Questions concerning billings and other fiscal matters should be directed to (name of fiscal intermediary). Questions related to the Conditions of Participation for CAHs should be referred to your SA.

We welcome your participation as a CAH in the Medicare program.

Sincerely,

(Associate Regional Administrator or Equivalent)

cc:
Fiscal Intermediary
Regional Administrator, Region _____
_____ State Department of Health

Part II: Exhibit 5
Model Letter: CAH Denial Letter

Name/Title of CAH Administrator, CEO, or Responsible Individual
Name of CAH
Street Address
City, State, Zip Code

Dear_____:

After a careful review of the facts, the Health Care Financing Administration (HCFA) has determined that the (name of CAH) no longer meets the requirements for participation as a provider of services as a Critical Access Hospital (CAH) in the Medicare program under "Title XVIII of the Social Security Act (the Act).

To continue to participate in the Medicare program, a CAH must meet the appropriate statutory provisions of §1820 of the Act and be in compliance with the Conditions of Participation (CoPs) at 42 CFR Part 485. CAHs with swing-bed approvals must also comply with the skilled nursing facility requirements for CAHs at 42 CFR 485.645.

We find that (name of CAH) does not meet the requirement(s) contained in (insert the specific requirement(s) that have not been met and a brief explanation of the circumstances of noncompliance).

The (name of State agency) which certifies to HCFA whether CAHs meet the CoPs at 42 CFR Part 485, has discussed the (state the specific CoP(s)) with you on numerous occasions. Based on the record of the State agency's visits, findings, and recommendations, we have determined that the requirement(s) is/are not met now and is not likely to be met within an acceptable time.

The date on which the agreement terminates is (date of termination). The Medicare program will not make payment for inpatient CAH services furnished for patients admitted after the (date of termination). For patients admitted prior to (date of termination), payment may continue to be made for a maximum of 96 hours for CAH inpatient services furnished on or after (date of termination). For swing-bed patients receiving a SNF level of care who are admitted prior to (date of termination), payment may continue to be made for a maximum of 30 days after (date of termination). You should submit, as soon as possible, a list of names and Medicare claim numbers of beneficiaries in your CAH on (date of termination) to the (name and address of HCFA regional office involved) to facilitate payment for these individuals.

We will publish a public notice of termination in the (name of local newspaper). You will be advised of the publication date for the notice.

You may, of course, take steps to meet the participation requirements and establish the CAH's eligibility to participate as a provider of services. The (State agency) is available to provide assistance you may need in order to accomplish this.

If you wish to be readmitted to the program, you must demonstrate to the (State agency) and HCFA that you are able to maintain compliance. Readmission to the program will not be approved until you are able to demonstrate compliance for a period of not less than (insert number of days) consecutive days.

MEDICARE RURAL HOSPITAL FLEXIBILITY PROGRAM

If you do not believe this determination is correct, you may request a hearing before an administrative law judge of the Department of Health and Human Services, Department Appeals Board. Procedures governing this process are set out in the regulations at 42 CFR 498.40 et. seq. A written request for a hearing must be filed no later than 60 days from the date of receipt of this letter. For expedited handling, such a request may be made to the following:

(Associate Regional Administrator of Equivalent)
(Street Address)
(City, State, Zip Code)

At your option, you may instead submit a hearing request directly (accompanied by a copy of this letter) to the following address. Send a copy of your request to this office also.

Departmental Appeals Board, Civil Remedies Division
Room 637-D, HHH Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

ATTN: Director, Departmental Appeals Board

A request for a hearing should identify the specific issues, and the findings of fact and conclusions that you consider to be incorrect. You may be represented by counsel at a hearing at your own expense.

We will forward your request to the Chief Administrative Law Judge in the Office of Hearings and Appeals.

If you have any questions concerning this letter, please contact (name of contact) at (phone number).

Sincerely,

(Associate Regional Administrator of Equivalent)

Enclosure: Form HCFA-2567, Statement of Deficiencies

cc:

Fiscal Intermediary
State Department of Health
HCFA Central Office

PART III-INTERPRETIVE GUIDELINE - CRITICAL ACCESS HOSPITALS

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
C150	**§485.608 Condition of participation: Compliance with Federal, State, and local laws and regulations.** The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations.	Interpretive Guideline §485.608 Failure of the CAH to meet a Federal, State or local law may only be cited when the Federal, State or local authority having jurisdiction has made both a determination of noncompliance and has taken a final adverse action as a result. Notify the HCFA regional office (RO) if you suspect that you have observed noncompliance with an applicable Federal law related to the CAH. The RO will notify the appropriate Federal agency of your observations.
C151	(a) Standard: Compliance with Federal laws and regulations. The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.	Survey Procedures and Probes §485.608(a) Refer suspected violation of Federal law to the HCFA RO for referral to the appropriate Federal agency.
C152	(b) Standard: Compliance with State and local laws and regulations. All patient care services are furnished in accordance with applicable State and local laws and regulations.	Interpretive Guideline §485.608(b) There are wide variations in the States' practice acts relative to the extent to which physicians may delegate responsibilities to nurse practitioners, clinical nurse specialists, and physician assistants. Some states have updated their practice acts to include definitions and specific references to permitted/prohibited activities, supervision/guidance required by a physician, and local situations in which nurse practitioners, clinical nurse specialists, and physician assistants may function. Survey Procedures and Probes §485.608(b) Prior to going on the survey, determine what professional specialists provide patient care services at the CAH and review State practice Act requirements. Interpretations needed on specific aspects of the State's practice Act should be sought through the State regulatory agency or board(s) dealing with the practice and profession. In situations where State law is silent, or where State law does not specifically prohibit the functioning of a physician assistant, clinical nurse specialist, or a nurse practitioner with medical direction by a physician and with the degree of supervision, guidance, and consultation required by CAH regulations, the surveyor may consider this standard as being met.

PART III-INTERPRETIVE GUIDELINES - CRITICAL ASSESS HOSPITALS

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
C153	(c) Standard: Licensure of CAH. The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.	Survey Procedures and Probes §485.608(c) If State law provides for licensure of CAHs, ask the State licensing agency if the CAH is currently licensed and request a copy of the license for the State agency file.
C154	(d) Standard: Licensure, certification or registration of personnel. Staff of the CAH are licensed, certified, or registered in accordance with applicable State and local laws and regulations.	Survey Procedures and Probes §485.608(d) Review CAH policies regarding certification, licensure, and registration of personnel. Are the CAH policies compliant with State and local laws? Are the personnel in compliance with CAH policy? Review personnel files to see if personnel licenses, certifications or registrations are current. How does the CAH ensure, in accordance with applicable State and local laws and regulations, that all staff have current licenses, certifications and/or registrations?
C160	**§485.610 Condition of participation: Status and Location.**	Interpretive Guideline §485.610 This COP applies only to initial surveys.
C161	(a) Standard: Status. The facility is a public or nonprofit hospital.	
C162	(b) Standard: Location. The CAH meets the following requirements-- (1) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under the regulations in §412.62(f) of this chapter.	Interpretive Guideline §485.610(b)(1) and (2) "Urban" as defined at 42 CFR 412.62(f), means a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget, or the following New England Counties: Litchfield County, Connecticut; York County, Maine; Merrimack County, New Hampshire; Newport County, Rhode Island; and Fagadahoe County, Maine. A current Bureau of the Census map showing all MSAs in the United States is available through the

PART III-INTERPRETIVE GUIDELINES - CRITICAL ACCESS HOSPITALS

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
C162 Cont.		Government Printing Office (GPO). This publication can be ordered through the GPO Order and Information Desk by calling 1-202-783-3238. Refer to GPO Stock No. 003-024-6506-1. Also a listing of telephone contacts at the Census Bureau ROs and State and Local Data Centers is contained in the GPO publication entitled, "U.S. Bureau of the Census Telephone Contacts for Data Users." This publication may be ordered through the telephone number shown above. When ordering, refer to GPO Stock No. 750-064/80025. "Urban area", as defined at 42 CFR 412.63(b), applies to CAHs located within a MSA or NECMA that crosses census division boundaries. In such cases, the MSA or NECMA in which the CAH is located is deemed to belong to the census divisions in which most of the hospitals within the MSA or NECMA are located. Survey Procedures and Probes §485.610(b) Determine that a CAH meets the basic location requirement prior to scheduling the survey. The appropriate RO will reverify the location requirement at §485.610(b) prior to approving a CAH for Medicare certification.
C163	(2) The CAH is not deemed to be located in an urban area under §412.63(b) of this chapter.	Survey Procedures and Probes §485.610(b)(2) and (3) After it has been determined that the CAH is not located in an MSA or in an urban area under §412.62(f), contact the appropriate regional office, Division of Medicare, to determine if the CAH is deemed to be located in an urban area under §412.63(b) or has been classified an urban hospital for purposes of the standardized payment amount or by the HCFA Medicare Geographic Classification Review Board.
C164	(3) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount or by the HCFA Medicare Geographic Classification Review Board under §412.230(e) of this chapter, and is not among a group of hospitals that have been redesignated to an adjacent urban area under §412.232 of this chapter.	

PART III-INTERPRETIVE GUIDELINES - CRITICAL ACCESS HOSPITALS

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
C165	(4) The CAH is located more than a 35 mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15 mile drive) from a hospital or another CAH, or the CAH is certified by the State as being a necessary provider of health care services to residents in the area.	Interpretive Guidelines §485.610(b)(4) One may reasonably consider a road "secondary" if it is not an Interstate, U.S., or State highway.
C170	**§485.612 Condition of participation: Compliance with hospital requirements at time of application.** The hospital has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.	Interpretive Guideline §485.612 This COP applies only to initial surveys. A hospital with a Medicare participation agreement that applies to the State for designation as a CAH must remain in compliance with the Medicare hospital Conditions of Participation under Part 482 of this chapter until such time that it certified as a CAH by HCFA.
C190	**§485.616 Condition of participation: Agreements.**	Interpretive Guideline §485.616 Section 485.603 defines a rural health network as an organization that includes at least one hospital that the State has designated or plans to designate as a CAH, and at least one hospital that furnishes acute care (hospital) services. Survey Procedures and Probes §485.616(a)(1) - (3) If the CAH is a member of a rural health network that has a communications system, ask to see the agreement required at §485.616.
C191	(a) Standard: Agreements with network hospitals	

PART III-INTERPRETIVE GUIDELINES - CRITICAL ACCESS HOSPITALS

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
C191 Cont.	In the case of a CAH that is a member of a rural health network as defined in §485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for--	How does the CAH participate with other hospitals and facilities in the network communications system? Is a communications log kept at the facility? Ask staff if there have been difficulties in contacting network members. If so, ask how the CAH deals with communications delays. What evidence demonstrates that CAH staff can operate communications equipment? How does the network's communications system compare with any on line and available communications equipment in the CAH? When the network communications system is down (i.e., not in operation), how does the CAH communicate and share patient data with other network members? Review any policies and procedures related to the use of or possible problems with the operation of any communications system. How is the CAH staff educated on the use of any communication system utilized in the facility? What type of agreement does the CAH have with the local EMS service? Review any written agreements for extent of service.
C192	(1) Patient referral and transfer;	
C193	(2) The development and use of communication systems of the network, including the network's system for the electronic sharing of patient data; and telemetry and medical records, if the network has in operation such a system; and	
C194	(3) The provision of emergency and non-emergency transportation among the facility and the hospital.	
C195	(b) Standard: Agreement for credentialing and quality assurance. Each CAH shall have an agreement with respect to credentialing and quality assurance with at least-- (i) One hospital that is a member of the network; (ii) One PRO or equivalent entity; or (iii) One other appropriate and qualified entity identified in the State rural health care plan.	Survey Procedures and Probes §485.616(b) Review any agreements related to credentialing or quality assurance to determine the level of assistance to be provided and the responsibilities of the CAH. Review procedures and policies for how information is to be utilized, obtained, and how confidentiality of information will be maintained.

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C200	**§485.618 Condition of participation: Emergency services.** The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.	Survey Procedures and Probes §485.618 Review any policies and procedures for emergency services in the CAH. What evidence indicates that the CAH is capable of providing necessary emergency care for its inpatients and outpatients? Review a sample of patient records for patients treated in the emergency services department to see if the CAH followed its own policies and procedures.
C201	(a) Standard: Availability. Emergency services are available on a 24-hour-a-day basis.	Interpretive Guideline §485.618(a) The law, at §1820(c)(2)(B)(ii) requires that a CAH "makes available 24 hour emergency services." This does not mean that the CAH must remain open 24 hours a day when it does not have inpatients (including swing-bed patients). A CAH that does not have inpatients may close (i.e., be unstaffed) provided that it has an effective system in place to meet the requirement at 42 CFR 485.618(d)(1) (i.e., a system to ensure that a practitioner with training and experience in emergency care is on call and immediately available by telephone or radio, and available on site within 30 minutes, 24 -hours- a-day). Survey Procedures and Probes §485.618(a) Ascertain by record review of patients admitted through the emergency department, interviews with staff, patients, and families, and/or observations, as applicable, that ER services were or were not made available in accordance with patient(s) presenting on a 24-hour-a-day basis. How does the CAH ensure that emergency services are made available on a 24-hour-a-day basis?
C202	(b) Standard: Equipment, supplies, and medication. Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items	Survey Procedures and Probes §485.618(b) How does the CAH ensure that the required equipment, supplies and medications are always readily available in the CAH? Interview staff and tour the ER to ascertain compliance and ability to provide emergency services.

	available must include the following--	

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C203	(1) Drugs and biologicals commonly used in life saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.	Survey Procedures and Probes (b)(1) How does the CAH ensure that staff know where drugs and biologicals are kept? How is the inventory maintained? Who is responsible for monitoring drugs and biologicals? How are drugs and biologicals replaced?
C204	(2) Equipment and supplies commonly used in life saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.	Survey Procedures and Probes §485.618(b)(2) How does the CAH ensure that equipment and supplies required at §485.618(b)(2) are readily available to staff? How does the CAH ensure that staff know where emergency equipment and supplies are kept? How is the supply inventory maintained? Who is responsible for monitoring supplies? How are supplies replaced? When was the last time emergency supplies were used? Is there an equipment maintenance schedule (e.g., for the defibrillator)? Ask staff if equipment has ever failed to work when needed. Examine sterilized equipment (e.g., tracheostomy sets) for expiration dates when applicable. Examine the oxygen supply system to determine functional capabilities. Check the force of the vacuum (suction) equipment to see that it is in operating condition.
C205	(c) Standard: Blood and blood products. The facility provides, either directly or under arrangements, the following--	Interpretive Guideline §485.618(c) The requirement at 42 CFR 485.618(c) can be met by a CAH by providing blood or blood products on an emergency basis at the CAH, either directly or through arrangement, if that is what the patient's condition requires. There is no requirement in the regulation for a CAH to store blood on site, although it may choose to do so. In some cases, it may be more practical to transport a patient to the

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C205 Cont.	(1) Services for the procurement, safekeeping and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours-a-day basis.	source of the blood supply than to bring blood to the patient at the CAH. A facility which has the capability of providing blood services on site would be in compliance with §485.618(c) even if, in virtually all cases, the patients were actually taken to the blood rather than vice versa. A CAH that stores blood on site will be surveyed under CLIA if tests subject to CLIA are conducted on the blood. A CAH that is only storing blood for transfusion and refers all related testing out to another laboratory is not performing testing as defined by CLIA. However, under this regulation, which refers to 42 CFR Part 493 Subpart K, it must ensure that blood is appropriately stored to prevent deterioration, including documenting refrigerator temperatures. The provision of blood services between the CAH and the testing laboratory should be reflected in the written agreement or arrangement between the two. Also, if the CAH is collecting blood, it must register with the Food and Drug Administration Survey Procedures and Probes §485.618(c)(1) "Availability" in this context, means that the blood and blood products must be accessible to CAH staff in time to effectively treat emergency patients at the CAH. In order to comply with this requirement, a CAH must demonstrate that it has the capability (i.e., an effective system is in place regardless of whether, in actual practice, it has been utilized) of making blood products available to its emergency patients 24- hours- a- day. A CAH could demonstrate that it has the capability of making blood products available for its emergency patients (e.g., demonstrating that it can perform type and compatibility procedures). If a CAH performs type and compatibility testing it must have the necessary equipment, (i.e., serofuge and heat block), as well as typing and crossmatching reagents, some of which have a 30-day expiration date. Another way for a CAH to meet this requirement would be to properly store 4 units of O negative packed red blood cells (the universal donor type) for availability at all times for emergencies only. CAHs that choose to store O negative packed red blood cells for emergency release of uncrossmatched blood will require a release form to be signed by a doctor, prior to transfusion, acknowledging that the blood has not been crossmatched for the patient. Facilities that elect to store units of O negative packed red blood cells should be able to demonstrate that they have an arrangement (e.g., with the Red Cross or other similar product provider) for the provision of fresh units of O negative packed red blood cells.

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C206	(2) Blood storage facilities that meet the requirements of 42 CFR Part 493, Subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.	Survey Procedures and Probes §485.618(c)(2) If blood banking services are provided on- site, what evidence show that the blood facility is under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy? For blood banking services provided under arrangement, what evidence show that the CAH medical staff and the person responsible for CAH operations have approved the arrangement?
C207	(d) Standard: Personnel. (1) There must be a practitioner with training or experience in emergency care on call and immediately available by telephone or radio contact, and available on- site within 30 minutes on a 24-hours-a-day basis.	Survey Procedures and Probes §485.618(d)(1) Review on- call schedules to determine how the CAH ensures that a staff member described in §485.618(d)(1) is on- call 24- hours -a- day and available on- site at the CAH within 30 minutes. Interview staff to determine how the CAH staff know who is on- call. What documentation demonstrates that a doctor of medicine or osteopathy, nurse practitioner or physician assistant with emergency training or experience has been on- call and available on- site at the CAH within 30 minutes? If there is evidence from interviews with CAH staff and/or documentation reviews that the 30 minute on -call requirement has not been met, expand the survey to include interviews with local officials (e.g., local volunteer rescue services, 911 dispatch services in the area, local government, etc.) to determine if there have been any instances when a properly trained or experienced CAH practitioner has not been available by telephone or radio or at the CAH within 30 minutes?

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C208	(2) The practitioner referred to in paragraph §485.618 (d)(1) must be a doctor of medicine or osteopathy, a physician assistant, or a nurse practitioner.	Survey Procedures and Probes §485.618(d)(2) Interview staff to determine what process is used by the CAH for scheduling or call- back, for practitioners referred to in §485.618(d)(1). How long does it take staff to get to the CAH after being called?
C209	(e) Standard: Coordination with emergency response systems. The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours-a-day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.	Interpretive Guideline §485.618(e) The CAH, not the local emergency response system (e.g., the local ambulance service), is responsible for ensuring that an effective procedure is in place to meet this requirement. Survey Procedures and Probes §485.618(e) What procedures are in place to ensure CAH coordination with emergency response systems to make available by telephone or radio contact, on a 24-hours-a-day basis, a doctor of medicine or osteopathy to receive emergency calls and provide medical direction in emergency situations? What evidence demonstrates that the procedures are followed and evaluated for effectiveness? Interview staff to see how an MD or DO is contacted when emergency instructions are needed. When was the last time such a situation occurred?
C210	**§485.620 Condition of participation: Number of beds and length of stay.**	
C211	(a) Standard: Number of beds. Except as permitted for CAHs having swing-bed agreements under §485.645 of this chapter, the CAH maintains no more than 15 inpatient beds.	Interpretive Guideline §485.620(a) CAHs with swing-bed may have up to 25 beds, but no more than 15 may be used for acute inpatient care at one time.

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C212	(b) Standard: Length of stay. The CAH discharges or transfers each inpatient within 96 hours after admission, unless a longer period is required because transfer to a hospital is precluded due to inclement weather or other emergency conditions. However, a PRO or equivalent entity may, on request, waive the 96 hour restriction on a case-by-case basis.	Survey Procedures and Probes §485.620(b) Review the control log containing information on patients coming to the CAH for treatment to ascertain if transfers or discharges are effectuated within 96 hours of admission. Review a sample of closed records to ascertain if there were any patient stays (excluding swing-bed patients) that exceeded 96 hours. If yes, what were the explanations regarding the reason(s) for the longer stays? Did the CAH seek waivers? If so, was a waiver obtained and documented? If you discover patients who were kept more than 96 hours without documentation in the medical record, copy relevant information and forward it to the regional office for review and further action, if appropriate.
C220	**§485.623 Condition of participation: Physical plant and environment.**	
C221	(a) Standard: Construction. The CAH is constructed, arranged, and maintained to ensure access to and safety of patients and provides adequate space in the provision of direct services.	Survey Procedures and Probes §485.623(a) During the tour of the facility, observe direct service areas for adequate space to ensure patient safety and to facilitate the provision of direct services required in §485.635(b) (i.e., patient examination and treatment areas, laboratory, radiology, and emergency services).
C222	(b) Standard: Maintenance. The CAH has housekeeping and preventive maintenance programs to ensure that-- (1) All essential mechanical, electrical, and patient care equipment is maintained in safe operating condition;	Survey Procedures and Probes §485.623(b)(1) How does the CAH ensure that its equipment (e.g., boiler room equipment, kitchen refrigerator/freezer, laundry equipment, etc.) is properly maintained in safe operating condition?
C223	(2) There is proper routine storage and prompt disposal of trash;	Survey Procedures and Probes §485.623(b)(2) How does the CAH ensure that trash, including contaminated materials, is disposed of promptly and properly?
C224	(3) Drugs and biologicals are appropriately stored;	Survey Procedures and Probes §485.623(b)(3)

		What standards, guidelines, State and Federal law is the CAH following to ensure that drugs and biologicals are appropriately stored (e.g., properly locked)?

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C225	(4) The premises are clean and orderly; and	Interpretive Guideline §485.623(b)(4) "Clean and orderly" means an uncluttered physical environment where patients and staff can function safely (e.g., equipment and supplies stored in proper spaces, not in corridors, spills not left unattended or identified, no floor obstructions) and is neat and well kept (e.g., no peeling paint, visible water leaks, plumbing problems).
C226	(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.	Survey Procedures and Probes §485.623(b)(5) What recommendations, standards, or guidelines does the CAH use for ventilation, lighting and temperature controls? Review maintenance records for repeated difficulties in ventilation, lighting, and temperature control without effective resolution.
C227	(c) Standard: Emergency procedures. The CAH assures the safety of patents in non-medical emergencies by-- (1) Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;	Survey Procedures and Probes §485.623(c)(1) How does the CAH ensure that all personnel on its staff, including new additions to the staff, are trained to manage non- medical emergencies? Ask facility staff what they are supposed to do in case of an emergency such as a tornado or a blizzard. Review staff training documents and inservice records to confirm training. Coordinate with other survey team members to ensure all staff are trained.
C228	(2) Providing for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas;	Survey Procedures and Probes §485.623(c)(2) How does the CAH provide emergency power? Can the emergency generator provide power for emergency equipment and lighting in the emergency room? Review maintenance records and facility specific policies and procedures or test runs and frequency of test runs on emergency equipment.
C229	(3) Providing for an emergency fuel and water supply; and	Survey Procedures and Probes §485.623(c)(3) and (4) Interview staff concerning the availability of emergency fuel and water supplies. Review any arrangements or agreements to determine the scope of services to be provided. Review policies for procedures addressing specific conditions for the area the CAH is located in (e.g., snowbound facility and spring flooding).
C230	(4) Taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.	

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C231	(d) Standard: Life safety from fire. (1) Except as provided in paragraphs §485.623(d)(2) and (3) of this section, the CAH must meet the requirements of Chapter 12, New Health Care Occupancy, or Chapter 13, Existing Health Care Occupancy, of the 1985 edition of the Life Safety Code of the National Fire Protection Association. Incorporation by reference to the 1985 edition of the National Fire Protection Association's Life Safety code (published February 7, 1985, ANSI/NFPA 101) was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. The Code is available for inspection at the HCFA Information Resource Center, 7500 Security Boulevard, Room C2-07-13, Central Building, Baltimore, Maryland 21244-1850 and the Office of the Federal Register, 800 North Capital Street, NW, Suite 700, Washington, D.C. Copies may be obtained from the National Fire Protection Association, Batterymarch Park, Quincy, Mass. 02209. If any changes in this code are also incorporated by reference, a document to that effect will be published in the Federal Register.	Survey Procedures and Probes §485.623(d)(1) Survey the entire building occupied by the CAH unless there is a 2-hour firewall separating the space designated as the CAH from the remainder of the building. A 2-hour floor slab does not count, it must be a vertical firewall to constitute a separate building or part of a building.
C232	(2) Any CAH that as a hospital on or before November 26, 1982, complied, with or without waivers, with the requirements of the 1967 edition of the Life Safety Code, or after November 26, 1982, and on or before May 9, 1988, complied with the 1981 edition of the Life Safety Code is considered to be in compliance with this standard as long as the	

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C232 Cont.	CAH continues to remain in compliance with that edition of the Code. The 1967 and 1981 editions of the Life Safety Code are available for inspection at the HCFA Resource Information Center, 7500 Security Boulevard, Room C2-07-13, Central Building, Baltimore, Maryland 21244-1850.	
C233	(3) After consideration of State survey agency findings, HCFA may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.	Survey Procedures and Probes §485.623(d)(3) Review Waiver, if available.
C234	(4) The CAH maintains written evidence of regular inspection and approval by State and local fire control agencies.	Survey Procedures and Probes §485.623(d)(4) Review fire inspection reports and/or coordinate with LSC/environment surveyors.
C240	**§485.627 Condition of participation: Organizational structure.**	
C241	(a) Standard: Governing body or responsible individual. The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH's total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.	Survey Procedures and Probes §485.627(a) Review the organizational structure. Have the facility's operating policies been up dated to fully reflect its responsibilities as a CAH (e.g., the 96 hour transfer rule, PA responsibilities, provision of required CAH direct services)? What evidence (e.g., minutes of board meetings) demonstrates that the governing body or the individual who assumes responsibility for CAH operation is involved in the day-to- day operation of the CAH and is fully responsible for its operations?

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C242	(b) Standard: Disclosure. The CAH discloses the names and addresses of-- (1) Its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with Subpart C of part 420 of this chapter;	Survey Procedures and Probes §485.627(b)(1) Review policy(ies) for reporting changes of ownership. How does the CAH implement its policy or procedure for reporting changes in ownership to the State agency? Are there any inconsistencies on the Form HCFA -855 relative to demonstrated evidence of actual operations at the CAH?
C243	(2) The person principally responsible for the operation of the CAH; and	Survey Procedures and Probes §485.627(b)(2) How does the CAH implement its policy or procedure for reporting changes in operating officials to the State agency?
C244	(3) The person responsible for medical direction.	Survey Procedures and Probes §485.627(b)(3) How does the CAH implement its policy or procedure for reporting a change in medical director to the State agency?
C250	**§485.631 Condition of participation: Staffing and staff responsibilities.**	
C251	(a) Standard: Staffing. (1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.	Interpretive Guideline §485.631(a)(1) A CAH may operate with a doctor of medicine or osteopathy on staff with a PA, NP or CNS, however, it must still meet the requirements at §485.618(d)(1) (on- call and available on- site within 30 minutes) and §485.631(a)(4) (available to furnish patient care services during the hours of operation). Survey Procedures and Probes §485.631(a)(1) Review listings or organizational charts, if available, showing the names of all staff physicians, nurse practitioners, clinical nurse specialists and physician assistants on the CAH staff. Review work schedules showing normal CAH hours of operation and coverage by members of the CAH staff.

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C252	(2) Any ancillary personnel are supervised by the professional staff.	Survey Procedures and Probes §485.631(a)(2) Use organizational charts and staff interviews to determine how the CAH ensures that all ancillary personnel are supervised by the professional staff.
C253	(3) The staff is sufficient to provide the services essential to the operation of the CAH.	Survey Procedures and Probes §485.631(a)(3) How does the CAH ensure that staff coverage is sufficient to provide essential services at the facility (e.g., emergency services described at §485.618, direct services described at §485.635(b), and nursing services described at §485.635(d))? Review staffing schedules and daily census records.
C254	(4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.	Interpretive Guideline §485.631(a)(4) Section 485.635(b)(1) requires CAHs to provide "those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office." Low intensity outpatient service is provided as an example. In order to demonstrate compliance with §485.631(a)(4), a CAH must demonstrate that a doctor of medicine or osteopathy, PA, NP or CNS is physically present and prepared to treat patients at the CAH (e.g., when patients present at the CAH outpatient clinic during announced hours of outpatient clinic operation). Section 485.631(a)(4) does not require a CAH to have a physician or mid-level practitioner physically present in the facility 24- hours- per- day, nor does it require their presence 24-hours -per -day when the CAH has inpatients, including swing-bed patients. Survey Procedures and Probes §485.631(a)(4) If the CAH does not have regular announced hours of operation, ask the individual principally responsible for the operation of the CAH when the CAH is open to the public (e.g., to provide outpatient services), and conversely, when it is not open to the public. What kinds of arrangements have been made by the CAH to ensure that a physician or mid-level practitioner is available on- site at all times the CAH operates to furnish patient care services?
C255	(5) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients.	Interpretive Guideline §485.631(a)(5) If a nurse practitioner is on duty in the CAH, both requirements at §485.631(a)(4) and (5) are met. If a physician assistant is on duty, §485.631(a)(4) is met, but in order for the CAH to meet §485.631(a)(5), a registered nurse, clinical nurse specialist or licensed practical nurse must also be on duty when the CAH has one or more inpatients.

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C255 Cont.		Survey Procedures and Probes §485.631(a)(5) Review nursing staff schedules to ensure that a registered nurse, clinical nurse specialist or licensed practical nurse is on duty whenever the CAH has one or more inpatients.
C256	(b) Standard: Responsibilities of the doctor of medicine or osteopathy. (1) The doctor of medicine or osteopathy--	
C257	(i) Provides medical direction for the CAH's health care activities and consultation for the medical supervision of the health care staff;	Interpretive Guideline §485.631(b)(1)(i) Section 485.631(a)(1) requires a CAH to have a doctor of medicine or osteopathy on its staff. That individual must perform all of the medical oversight functions described in §485.631(b). Survey Procedures and Probes §485.631(b)(1)(i) What evidence demonstrates that a doctor of medicine or osteopathy provides medical direction for the CAH's health care activities and is available for consultation and supervision of the CAH health care staff?
C258	(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH's written policies governing the services it furnishes;	Survey Procedures and Probes §485.631(b)(1)(ii) What evidence demonstrates that the doctor of medicine or osteopathy has participated in the development of policies governing CAH services? How does the CAH ensure that these policies are periodically reviewed by the doctor of medicine or osteopathy?
C269	(iii) In conjunction with the physician assistant and/or nurse practitioner member(s), periodically reviews the CAH's patient records, provides medical orders, and provides medical care services to the patients of the CAH; and	Survey Procedures and Probes §485.631(b)(1)(iii) How does the CAH ensure that the doctor of medicine or osteopathy periodically reviews CAH patient records in conjunction with staff mid-level practitioners and provides medical care to CAH patients? What evidence demonstrates that there is a periodic review of patient records by the CAH physician?

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C260	(iv) Periodically reviews and signs the records of patients cared for by nurse practitioners, clinical nurse specialists, or physician assistants.	Interpretive Guideline §485.631(b)(1)(iv) The CAH physician must review and sign all inpatient records for patients cared for by mid-level practitioners at the CAH. This function could be performed during the site visit required at §485.631(b)(2). The CAH physician is not required to review and sign all outpatient records for patients cared for by mid-level practitioners at the CAH. If the CAH has an unusually high volume of outpatients (i.e., 100 or more cases during a two week period) a random sample of 25 percent is sufficient. If State practice laws require higher standards for physician oversight of mid-level practitioners, the CAH must comply with those standards. Survey Procedures and Probes §485.631(b)(1)(iv) Prior to the survey, review all mid-level practitioner practice law requirements regarding records and orders to determine higher review standards. How does the CAH ensure that the doctor of medicine or osteopathy reviews and signs all inpatient records for patients cared for by CAH mid-level practitioners? How does the CAH ensure that a doctor of medicine or osteopathy reviews and signs outpatient records for patients treated by mid-level practitioners in compliance with either the sampling methodology described above or State practice laws, if those laws mandate a higher review standard? What is the CAH policy regarding periodic reviews?
C261	(2) A doctor of medicine or osteopathy is present for sufficient periods of time, at least once in every two week period (except in extraordinary circumstances) to provide the medical direction, medical care services, consultation, and supervision described in this paragraph, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the CAH. A site visit is not required if no patients have been treated since the last site visit.	Interpretive Guideline §485.631(b)(2) If specific State practice laws or regulations require that a physician visit a CAH more frequently than once every two weeks, the CAH must meet those requirements. Survey Procedures and Probes §485.631(b)(2) What documentation shows that the physician visits the facility at least once every two weeks? If the physician has not visited the facility due to extraordinary circumstances, is this documented in the CAH records? How does the CAH ensure that the physician is available by telephone or radio contact for consultation, assistance and/or patient referral?
C262	(c) Standard: Physician assistant, nurse practitioner, and clinical nurse specialist responsibilities.	

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C262 Cont.	(1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH's staff--	
C263	(i) Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and	Survey Procedures and Probes §485.631(c)(1)(i) Interview the NPs, CNSs, and/or PAs to ascertain their level of involvement in CAH policy development, execution, and periodic review. Does the CAH ensure that policies are updated to remain consistent with State standards of practice requirements for PAs, NPs, and CNSs? NOTE: Participation by PAs, NPs or CNSs is not required unless the CAH has these practitioners on staff.
C264	(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.	Survey Procedures and Probes §485.631(c)(1)(ii) How does the CAH ensure that PAs, NPs, and/or CNSs at the CAH participate with a doctor of medicine or osteopathy in the review of their patients' health records?
C265	(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy--	
C266	(i) Provides services in accordance with the CAH's policies; and	Survey Procedures and Probes §485.631(c)(2)(i) Review policies and procedures. Interview mid-level practitioners to gauge their knowledge and application of CAH policies.
C267	(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.	Survey Procedures and Probes §485.631(c)(2)(ii) What are the CAH's policies for transferring patient health records to another facility? How does the CAH ensure that patients are referred when they need services not available at the CAH? How is the CAH staff made aware of available referral sources?

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C268	(3) Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission.	Survey Procedures and Probes §485.631(c)(3) What system is in place to ensure notification of a doctor of medicine or osteopathy when inpatients are admitted?
C270	**§485.635 Condition of participation: Provision of services.**	
C271	(a) Standard: Patient care policies. (1) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.	Survey Procedures and Probes §485.635(a)(1) Review CAH health care services policies. Review sampled records (sample size is described at §485.638(a)(2), Tag No. C302) and observe staff delivering health care services to patients. What evidence indicates that patients are receiving care in accordance with written policies for health care services consistent with applicable State law?
C272	(2) The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of §485.631(a)(1); at least one member is not a member of the CAH staff.	Interpretive Guideline §485.635(a)(2) A CAH with a full time physician is not required to have mid-level practitioner on staff, and therefore, would not have to obtain the services of a mid-level practitioner on a contractual or voluntary basis to participate in writing the facility's health care services policies. Survey Procedures and Probes §485.635(a)(2) Review any meeting minutes to determine group composition and to ascertain the extent of the group's interactions with the CAH. Interview the Director of Nursing to determine the extent of her interactions with this group concerning policy development.
C273	(3) The policies include the following: (i) A description of the services the CAH furnished directly and those furnished through agreement or arrangement.	Interpretive Guideline §485.635(a)(3)(i) Policies should clearly explain what type of health care services are available at the CAH and which are furnished through agreements or arrangements. For example, statements like "taking complete medical histories, providing complete physical examinations, laboratory tests including" (with a list of tests provided) would satisfy this requirement.

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C273 Cont.		Arrangement and/or agreements, include services provided through formal contracts, joint ventures, informal agreements, or lease arrangements. Additional services furnished through referral should be clearly described in statements such as: "arrangements have been made with hospital X for CAH patients to receive the following services" (with a specific list of specialized diagnostic and laboratory testing, specialized therapy).
C274	(ii) Policies and procedures for emergency medical services.	Interpretive Guideline §485.635(a)(3)(ii) Policies should show how the CAH will meet all of its emergency services requirements at §485.618.
C275	(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.	Interpretive Guideline §485.635(a)(3)(iii) Guidelines for the medical management of health problems should include a description of the scope of medical acts which may be undertaken by the PA, NP or CNS. Guidelines represent an agreement between the doctor of medicine or osteopathy providing the CAH's medical direction and the CAH's PA, NP and/or CNS relative to the privileges and limits of those acts of medical diagnosis and treatment which may be undertaken with direct physician supervision. Guidelines should describe the regimens to follow and also stipulate the condition in the illness or health care management at which consultation or referral is required. Regardless of the format used by the CAH for its medical management guidelines, they should include the following essential elements: o They should be comprehensive enough to cover most health problems that patients usually refer to a physician; o They should describe the medical procedures available to the PA, NP and/or CNS; o They should describe the medical conditions, signs, or developments that require consultation or referral; and o They should be compatible with State laws. Survey Procedures and Probes §485.635(a)(3)(iii) What evidence demonstrates that the CAH's guidelines for medical management of health problems accurately reflect the actual clinical capabilities of the facility? What evidence demonstrates that the guidelines are followed?

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C276	(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.	Interpretive Guideline §485.635(a)(3)(iv) "In accordance with accepted professional principles" means patient care standards promoted by national, State and local professional associations regarding the clinical use of drugs and biologicals. This encompasses control procedures, proper labeling and disposal procedures. Survey Procedures and Probes §485.635(a)(3)(iv) How does the CAH ensure that there are current and accurate records of receipt and disposition of all scheduled drugs? Who in the CAH has access and/or keys to the drug storage area? How does the CAH ensure there are no outdated, mislabeled or unusable drugs and biologicals in the drug storage areas and pharmacy? If the CAH has a pharmacy, interview the individual identified to direct the management of pharmaceuticals. Is this individual properly identified in the CAH written policies and procedures? Inspect the pharmacy. Ask how pharmaceuticals are delivered, received and stocked. How does the CAH store drugs and biologicals? How does the CAH ensure there are adequate records to account for pharmaceuticals removed and administered?
C277	(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.	Interpretive Guideline §485.635(a)(3)(v) Written procedures should require that medication errors and adverse drug reactions be reported immediately to the practitioner who ordered the drug. An entry, including the medication administered and the drug reaction, should be entered into the patient's medical record. Unexpected or significant adverse drug reactions should also be reported to the Food and Drug Administration.
C278	(vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.	Interpretive Guideline §485.635(a)(3)(vi) Because of the risk of nosocomial infection, a viable system would, of necessity, include an active surveillance program of specific measures for prevention, early detection, control, education and investigation of infections and communicable diseases in the CAH. There should also be a mechanism to evaluate the program(s) and take corrective action. The system should be facility wide (i.e., including all inpatient and outpatient areas) and be specific to each separate department in the facility. The CAH should institute the current recommendations of the Centers for Disease Control and Prevention (CDC) relative to specific infection(s) and communicable disease(s). The CAH may

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C278 Cont.		refer to the current reference on infection control published by the CDC: Guideline for Prevention and Control of Nosocomial Infections (most recent edition). Survey Procedures and Probes §485.635(a)(3)(vi) What system is in place in the CAH to identify, report, investigate and control infections and communicable diseases? How is the infection control program incorporated into the facility-wide QA program described at §485.641(b)? What are the procedures to resolve identified problems involving infections and communicable diseases within the facility? Ask facility staff member(s) responsible for this activity: o How do you assess the risk for infections and communicable diseases? o How do you identify patients at risk for infections and communicable diseases? o How are health care workers (HCWs) on staff (including part time staff) educated about infections and communicable diseases? o How are HCWs screened for communicable diseases? o How are HCWs evaluated when they are exposed to nontreated communicable diseases? o How does the CAH provide a safe environment and treatment measures that are consistent with the most recent CDC recommendations for the identified infection and/or communicable diseases? o How are all culture results routed to the person responsible for the infection control program? Select a small sample of incidents of infection reports and determine if the incidents were investigated and resolved according to the CAH's system (e.g., starting with a review of microbiology reports, patients' medical records or other data) and if the investigation might have been expanded to collect information from other parts of the facility.
C279	(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of §483.25(i) is met with respect to inpatients receiving post hospital SNF care.	Interpretive Guidelines §485.635(a)(3)(vii) A CAH is not required to prepare meals itself and is free to obtain meals under contract with another supplier, but the CAH is responsible for the quality of arranged services on the same basis as if those services had been provided by CAH employees.

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C279 Cont.		Survey Procedures and Probes §485.635(a)(3)(vii) What policies and procedures are in place to govern the delivery of dietary services? What recognized dietary practices are followed in the CAH to ensure that patients' (including swing-bed patients) dietary needs are met? Review the dietary manual for current diet plans and approval of these plans by the medical staff. How does the CAH ensure that practitioners' dietary orders are implemented? Review a sample of patient (including swing-bed patients) menus to determine if they reflect the dietary orders of each patient's practitioner.
C280	(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph §485.635(a)(2) of this section, and reviewed as necessary by the CAH.	Survey Procedures and Probes §485.635(a)(4) What evidence demonstrates the patient care policies are reviewed on an annual basis by the professional group described in §485.635(a)(2) (e.g., meeting notes, memoranda initialed and dated by staff members, etc)? How does the CAH ensure that recommended revisions of patient care policies are implemented?
C281	(b) Standard: Direct services. (1) General. The CAH staff furnishes as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.	Interpretive Guideline §485.635(b) "Direct services" refers to a minimum set of services (i.e., services listed at §485.635(b)) at the CAH provided through the use of CAH personnel. Survey Procedures and Probes §485.635(b)(1)-(4) Through what process are these services provided? What is the daily time period these services are offered? How are these services incorporated into the facility-wide QA program described at §485.641(b)?

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C282	(2) Laboratory services. The CAH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under Section 353 of the Public Health Service Act (42 U.S.C. 236(a)) (See the laboratory requirements specified in Part 493 of this Chapter). The services provided include-- (i) Chemical examination of urine by dipstick or tablet method or both (including urine ketones); (ii) Hemoglobin or hematocrit; (iii) Blood glucose; (iv) Examination of stool specimens for occult blood; (v) Pregnancy tests; and (vi) Primary culturing for transmittal to a certified laboratory.	Interpretive Guideline §485.635(b)(2) Basic laboratory services in §485.635(b)(2) must be provided directly at the CAH in order to facilitate the immediate diagnosis and treatment of the patient. The CAH must have a current CLIA certificate for those tests required at §485.635(b)(2). Additional laboratory services may be provided in the CAH or by arrangement, but in all cases, these services must meet the laboratory requirements found in 42 CFR Part 493 of this chapter. Survey Procedures and Probes §485.635(b)(2) For this requirement, ascertain that the CAH has the capability of performing the tests listed at §485.635(b)(2) by reviewing logs and records in the laboratory. Also, ascertain that the laboratory has the appropriate CLIA certificate for the tests listed at §485.635(b)(2). A separate CLIA survey will determine that the tests are performed in compliance with 42 CFR 493 of this chapter.
C283	(3) Radiology services. Radiology services furnished at the CAH are provided as direct services by staff qualified under State law and do not expose CAH patients or staff to radiation hazards.	Interpretive Guidelines §485.635(b)(3) A CAH is required to provide only those radiologic services that are actually needed to meet the minimal requirements as a CAH. Survey Procedures and Probes §485.635(b)(3) How does the CAH ensure that radiology services are provided by staff qualified under State law? How does the CAH determine the types of procedures each individual is permitted to perform in the department and who is permitted to interpret the results?

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C283 Cont.		How does the CAH provide for adequate shielding for patients, personnel and facilities? How does the CAH provide for adequate storage, use, and disposal of radioactive materials? How does the CAH ensure that there are periodic inspections, and prompt identification and correction of hazards? How does the CAH prevent and monitor patient and staff exposure to radioactive hazards?
C284	(4) Emergency procedures. In accordance with the requirements of §485.618, the CAH provides as direct services, medical emergency procedures as a first response to common life-threatening injuries and acute illness.	Who is responsible for ensuring the availability of emergency equipment and supplies?
C285	(c) Standard: Services provided through agreements or arrangements. (1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including--	Interpretive Guideline §485.635(c)(1) Individual agreements or arrangements should be well defined, but need not be contractual. They should describe routine procedures (e.g., for obtaining outside laboratory tests); and there should be evidence in the agreement or arrangement that the governing body or responsible individual described in §485.627(a) is responsible for these services provided under agreement or arrangement. Individual agreements or arrangements should be revised when the nature and scope of services provided has changed.
C286	(i) Inpatient hospital care;	Survey Procedures and Probes §485.635(c)(1)(i) How does the CAH ensure that it has arrangements or agreements with one or more hospitals to provide inpatient care to its patients?
C287	(ii) Services of doctors of medicine or osteopathy;	Survey Procedures and Probes §485.635(c)(1)(ii) How does the CAH ensure that it has arrangements or agreements with one or more doctors of medicine or osteopathy to meet its requirements at §485.631(b)?
C288	(iii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH; and	Interpretive Guideline §485.635(c)(1)(iii) Laboratories that provide additional diagnostic and clinical laboratory services to a CAH by agreement or arrangement must be in compliance with CLIA requirements in 42 CFR Part 493 of this chapter. These laboratories will be surveyed separately for compliance with Part 493.

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C288 Cont.		Survey Procedures and Probes §485.635(c)(1)(iii) How does the CAH ensure through arrangements or agreements that it can obtain specialized diagnostic and clinical laboratory services (in addition to those required in §485.635(b)(2)) that are necessary to provide care for its patients? How does the CAH ensure any laboratories providing services to CAH patients are in compliance with CLIA requirements?
C289	(iv) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.	Survey Procedures and Probes §485.635(c)(1)(iv) If the CAH has an outside contract for nutritional services, how does the CAH ensure that it has arrangements or agreements for the provision of nutritional services that meet its requirements in §485.635(a)(3)(vii) and (if it has swing-bed patients) §483.25(i)?
C290	(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.	Survey Procedures and Probes §485.635(c)(2) Review a sample of medical records of patients who were treated and transferred from the CAH. What documentation shows that-- o Transferred patients were accepted and provided with inpatient care, as needed, at hospitals to which they were transferred? o Patients referred for diagnostic and/or laboratory tests had these tests performed as requested by the practitioner responsible for the patient? o Physicians and/or suppliers of services are providing services for the CAH in the manner described in the arrangement or agreement?
C291	(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.	Survey Procedures and Probes §485.635(c)(3) How does the CAH ensure that is has arrangements or agreements that are current? Review any arrangements or agreements to determine if the nature and scope of services defined is being provided to CAH patients.
C292	(4) The person principally responsible for the operation of the CAH under §485.627(b)(2) of this chapter is also responsible for the following-- (i) Services furnished whether or not they are furnished under arrangements or agreements;	Survey Procedures and Probes §485.635(c)(4)(i) How does the CAH ensure, (e.g., through operating policies and procedures, by- laws etc.) that the individual responsible for its operations under §485.627(b)(2) is responsible for all services provided through arrangements or agreements?

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C293	(ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.	Survey Procedures and Probes §485.635(c)(4)(ii) How does the CAH ensure that contracted services meet all of the CAH Conditions of Participation and standards for contracted services?
C294	(d) Standard: Nursing services. Nursing services must meet the needs of patients.	
C295	(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.	Survey Procedures and Probes §485.635(d)(1) Interview the registered nurse responsible for supervising the nursing care of the patients and ask the following-- o How are the specialized needs of patients determined? Who makes this determination? o How are staff assigned? o How are staff monitored to ensure that appropriately qualified staff provide the care needed? o How does the CAH ensure that care provided meets the needs of each patient? If temporary nursing staff are utilized, how are these staff oriented and supervised relative to CAH nursing procedures? Interview one or more temporary staff, if available, to determine if they are adequately familiar with CAH nursing requirements.
C296	(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.	Survey Procedures and Probes §485.635(d)(2) How does the CAH ensure that a registered nurse or (where State law permits) a physician assistant, supervises the nursing care for each patient? Interview the RN, CNS, NP or PA who is responsible for supervising and evaluating the nursing care for CAH patients. Ask to see staffing schedules for the one month period preceding the survey. How does the CAH ensure that staffing schedules correlate to the number and acuity of patients, including swing-bed patients? Take into account such things as the layout and size of the facility, number of inpatients (including swing-bed patients), intensity of illness and nursing needs, availability of LPNs, nurse aides, orderlies, and other resources for nurses as well as the training and experience of personnel.

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C297	(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or physician assistant, where permitted by State law, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.	Survey Procedures and Probes §485.635(d)(3) How does the CAH ensure that all orders to administer drugs, biologicals, and intravenous medications are signed by a practitioner permitted by State law to write and sign orders? How does the CAH ensure that its policies and procedures for the administration of drugs, biologicals and intravenous medications are followed? Review a sample of medication administration records to determine if they conform to the practitioner's orders. Observe the preparation of drugs and their administration to patients to determine if written procedures are followed in all instances. How is the administration of drugs, biologicals and intravenous medications regularly monitored for quality assurance purposes?
C298	(4) A nursing care plan must be developed and kept current for each inpatient.	Interpretive Guideline §485.635(d)(4) Nursing care plans should include all pertinent information about the patient, the priority of problems and the expected outcomes of nursing intervention. The plan should be revised as often as necessary to reflect the needs of the patient. Survey Procedures and Probes §485.635(d)(4) Select and review a sample (6-12) of nursing care plans for inpatients and swing-bed patients in the CAH. How does the CAH ensure that nursing care plans identify the nursing needs of the patients and ensure implementation of the attending practitioner's plan for medical care?
C300	**§485.638 Condition of participation: Clinical records.**	
C301	(a) Standard: Records system. (1) The CAH maintains a clinical records system in accordance with written policies and procedures.	

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C302	(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.	Survey Procedures and Probes §485.638(a)(2) For CAH re-surveys (i.e., surveys conducted after the first- time certification survey), examine a sample (at least 10 percent of the census but not more than 30) of CAH active and closed clinical records to determine if records are prepared and maintained in accordance with the requirements of §485.638(a)(2) and (4).
C303	(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.	Survey Procedures and Probes §485.638(a)(3) How does the staff member who is responsible for the CAH clinical records system ensure that the CAH meets the requirement at §485.638(a)(3)?
C304	(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable-- (i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;	Survey Procedures and Probes §485.638(a)(4)(i) For sampled records, are there properly executed informed consent forms, medical history, health status and care needs assessment, and summary in each record, as needed?
C305	(ii) Reports of physical examinations, diagnostic and laboratory test results, including laboratory services, and consultative findings;	For sampled records, are reports of physical examinations, diagnostic and laboratory test results, and consultative findings signed by the appropriate practitioner?
C306	(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatments; and	Interpretive Guideline §485.638(a)(4)(iii) The examples following the phrase, "other pertinent information" at §485.638(a)(4)(iii), are not provided as specific requirements for the CAH. They are listed to illustrate the kind of information that should be considered to meet the requirement for "other pertinent information."

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C307	(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.	Interpretive Guideline §485.638(a)(4)(iv) There should be a current list of authenticated signatures, as well as a list of computer codes and signature stamps (when used for authorship purposes) that have been authorized by the governing body and are protected by adequate safeguards. CAH policies and procedures should provide for appropriate sanctions for unauthorized or improper use of computer codes or signature stamps. Survey Procedures and Probes §485.635(a)(4)(iv) For sampled records, are there dated and authenticated signatures by appropriate physicians and/or mid-level practitioners, as needed?
C308	(b) Standard: Protection of record information. (1) The CAH maintains the confidentially of record information and provides safeguards against loss, destruction, or unauthorized use.	Survey Procedures and Probes §485.638(b)(1) How does the CAH ensure the confidentiality of records information and safeguard records? What precautions are taken to prevent unauthorized persons from gaining access to patient records?
C309	(2) Written policies and procedures govern the use and removal of records from the CAH and the condition for the release of information.	Survey Procedures and Probes §485.638(b)(2) Under what conditions are patients' records authorized to be removed from the CAH? How does the CAH enforce its written policies and procedures for the use and release of records?
C310	(3) The patients's written consent is required for release of information not required by law.	Survey Procedures and Probes §485.638(b)(3) Examine a sample of patient records and/or facility records of requests for information contained in patients records to determine if there are signed and dated consent forms when required.
C311	(c) Standard: Retention of records. The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending preceding.	Interpretive Guideline §485.638(c) Medical records must be retained in their original or legally reproduced form, including microfilm or optical disk systems, for a period of at least 6 years. Physician orders can be sent via facsimile to the CAH. No counter signature is necessary.

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C311 Cont.		Survey Procedures and Probes §485.638(c) How does the CAH ensure that records will be retained (e.g., through a written procedure) for at least 6 years from date of last entry?
C320	**§485.639 Condition of participation: Surgical services.** Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.	Interpretive Guideline §485.639 "In a safe manner" means that-- o The equipment and supplies are sufficient so that the type of surgery conducted can be performed in a manner that will not endanger the health and safety of the patient; o Access to operative and recovery areas is limited; o All individuals in the surgical area conform to aseptic techniques; o Appropriate cleaning is completed between surgical cases; o Suitable equipment is available for rapid and routine sterilization of operating room materials; o Sterilized materials are labeled, and stored in a manner to ensure sterility; and o Operating room attire is suitable for the kind of surgical cases performed. (Persons working in the operating suite must wear clean surgical costumes in lieu of their ordinary clothing.) Surgical costumes are to be designed for maximum skin and hair coverage. Survey Procedures and Probes §485.639 Policies and procedures should contain at a minimum: o Resuscitative techniques; o Aseptic technique and scrub procedures; o Care of surgical specimens; o Appropriate protocols for all surgical procedures, specific or general in nature, and include a list of equipment, materials, and supplies to properly carry out job assignments; o Procedures addressing the cleaning of operating rooms after each use; o Sterilization and disinfection procedures; o Acceptable operating room attire; o Care of anesthesia equipment; and o Special provision for infected or contaminated patients.

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C321	(a) Designation of qualified practitioners. The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by-- (1) A doctor of medicine or osteopathy, including an osteopathy practitioner recognized under section 1101(a)(7) of the Act; (2) A doctor of dental surgery or dental medicine; or (3) A doctor of podiatric medicine.	Survey Procedures and Probes §485.639(a) Review the surgical list of specific physician clinical privileges to determine if current. For sampled records, are procedures performed by appropriate physicians?
C322	(b) Anesthetic risk and evaluation. A qualified practitioner, as described in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of anesthesia and of the procedure to be performed. Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner as described in paragraph (a) of this section.	Survey Procedures and Probes §485.639(b) The medical record should confirm: o If laboratory studies were ordered as part of patient evaluation. The report should be part of the medical record or notation of the findings recorded on the chart. For general anesthesia, the evaluation should contain, at a minimum, a brief note regarding the heart and lung findings the day of surgery; and o Depending on the type of anesthesia and length of surgery, the postoperative check should include some or all of the following: - Level of activity; - Respirations; - Blood pressure; - Level of consciousness; - Patient color; and - Wound/dressing assessment, when appropriate.
C323	(c) Administration of anesthesia. The CAH designates the person who can administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope of practice laws.	Survey Procedures and Probes §485.639(c) The CAH indicates those persons qualified to administer anesthesia. What policies and procedures are in place to govern the administration of anesthesia?

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C324	(1) Anesthetics must be administered by-- (i) A qualified anesthesiologist; (ii) A doctor of medicine or osteopathy other than an anesthesiologist, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act; (iii) A doctor of dental surgery or dental medicine; (iv) A doctor of podiatric medicine; (v) A certified registered nurse anesthetist, as defined in §410.69(b) of this chapter; or (vi) An anesthesiologist's assistant, as defined in §410.69(b) of this chapter; or (vii) A supervised trainee in an approved educational program, as described in §§413.85 or 413.86 of this chapter.	Interpretive Guideline §485.639(c)(1) An approved educational program is a formal training program leading to licensure or certification in anesthesia that is recognized by the State.
C325	(2) In those cases in which a certified registered nurse anesthetist administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner. An anesthesiologist's assistant must be under the supervision of an anesthesiologist.	Survey Procedures and Probes §485.639(c)(2) How does the CAH ensure the operating practitioner understands and agrees to supervise the anesthetist when applicable?
C326	(d) Discharge. All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.	Interpretive Guideline §485.639(d) Any exceptions to this requirement must be made by the attending practitioner and annotated on the clinical record. Survey Procedures and Probes §485.639(d) What policies and procedures are in place to govern discharge procedures and instructions? How does the CAH ensure that patients receive discharge instructions?

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C330	**§485.641 Condition of participation: Periodic evaluation and quality assurance review.**	
C331	(a) Standard: Periodic evaluation. (1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of--	Survey Procedures and Probes §485.641(a)(1) How is information obtained to be included in the periodic evaluation? How does the CAH conduct the periodic evaluation? Who is responsible for conducting the periodic evaluation?
C332	(i) The utilization of CAH services, including at least the number of patients served and the volume of services;	Survey Procedures and Probes §485.641(a)(1)(i) How does the CAH ensure that the yearly program evaluation includes a review of all CAH services, the number of patients served and the volume of services provided?
C333	(ii) A representative sample of both active and closed clinical records; and	Interpretive Guideline §485.641(a)(1)(ii) "A representative sample of both active and closed clinical records" means not less than 10 percent of both active and closed patient records. Survey Procedures and Probes §485.641(a)(1)(ii) Who is responsible for the review of both active and closed clinical records? How are records selected and reviewed in the periodic evaluation? How does the evaluation process ensure that the sample of records is representative of services furnished? What criteria is utilized in the review of both active and closed records?
C334	(iii) The CAH's health care policies.	Survey Procedures and Probes §485.641(a)(1)(iii) What evidence demonstrates that the health care policies of the CAH are evaluated, reviewed and/or revised as part of the annual program evaluation?
C335	(2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.	Survey Procedures and Probes §485.641(a)(2) How does the CAH use the results of the yearly program evaluation? Were policies, procedures and /or facility practices added, deleted or revised as a result of the yearly program evaluation if needed?

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C336	(b) Standard: Quality assurance. The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that--	Survey Procedures and Probes §485.641(b) There is nothing in the requirement at §485.641(b) to preclude a CAH from obtaining QA through arrangement with a hospital (e.g., a hospital in the same rural health network). Whether the CAH has a freestanding QA program or QA by arrangement, all of the requirements at §485.641(b) must be met. If a CAH chooses to have a freestanding QA program, the QA program should be facility wide, including all departments and all services provided under contact. For services provided to the CAH under contract, there should be established channels of communication between the contractor and CAH staff. "An effective quality assurance program" means a QA program that includes: o Ongoing monitoring and data collection; o Problem prevention, identification and data analysis; o Identification of corrective actions; o Implementation of corrective actions; o Evaluation of corrective actions; and o Measures to improve quality on a continuous basis. Review a copy of the CAH QA plan and other documentation regarding QA activities, (e.g., meeting notes from QA committees, reports produced by the QA director and/or QA committees, if designated, and follow-up communication relative to corrective actions) to become familiar with the scope, methodology and organization of the CAH QA program.
C337	(1) All patient care services and other services affecting patient health and safety, are evaluated;	Survey Procedures and Probes §485.641(b)(1) Who is responsible to evaluate CAH patient care services? How are patient care services evaluated? What other services are evaluated? How does the CAH ensure quality assurance data is provided to the medical staff and governing body?
C338	(2) Nosocomial infections and medication therapy are evaluated;	Survey Procedures and Probes §485.641(b)(2) What methodology does the CAH use to evaluate nosocomial infections and medications therapy? Review committee meeting minutes for current issues or projects, etc.

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C339	(3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;	Survey Procedures and Probes §485.641(b)(3) How does the CAH ensure that the quality of care provided by mid-level practitioners in the CAH is evaluated by a doctor of medicine or osteopathy? How is clinical performance of mid-level practitioners evaluated? What evidence demonstrates that there is an ongoing evaluation of care provided by mid-level practitioners (e.g., reports, periodic written evaluation, QA meeting notes?) How does the reviewing physician inform the CAH if he/she determines that there are problems relative to the diagnosis and treatment provided by mid-level practitioners? What follow-up actions are called for in the QA plan?
C340	(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by-- (i) one hospital that is a member of the network, when applicable; or (ii) one PRO or equivalent entity; or (iii) one other appropriate and qualified entity identified in the State rural health care plan; and	
C341	(5)(i) The CAH staff considers the findings of the evaluations, including any findings or recommendations of the PRO, and takes corrective action if necessary.	Survey Procedures and Probes §485.641(b)(5)(i) Who is responsible for reviewing the PRO's findings and recommendations for the CAH? Who is responsible for ensuring that corrective actions are taken?
C342	(ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.	Survey Procedures and Probes §485.641(b)(5)(ii) and (iii) How does the CAH ensure that proper remedial actions are taken to correct deficiencies identified in the quality assurance program? Who is responsible for implementing remedial actions to correct deficiencies identified by the quality assurance program?
C343	(iii) The CAH documents the outcome of all remedial action.	How does the CAH document the outcome of any remedial action?

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C350	**§485.645 Special requirements for CAH providers of long-term care services ("swing-bed").** A CAH must meet the following requirements in order to be granted an approval from HCFA to provide post-hospital SNF care as specified in §409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section.	
C351	(a) Eligibility. A CAH must meet the following eligibility requirements-- (1) The facility has been certified as a CAH by HCFA under §485.606(b) of this subpart; and (2) The facility provides not more than 25 inpatient beds, and the number of beds used at any time for acute care inpatient services does not exceed 15 beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.	
C352	(b) Facilities participating as rural primary care hospitals (RPCHs) on September 30, 1997. These facilities must meet the following requirements-- (1) Notwithstanding paragraph (a) of this section, a CAH that participated in Medicare as a (RPCH) on September 30, 1997, and on that date had in effect an approval from HCFA to use its inpatient facilities to provide post-hospital SNF care may continue in that status under the same terms, conditions, and	

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C352 Cont.	limitations that were applicable at the time these approvals were granted.. 2) A CAH that was granted swing-bed approval under paragraph (b)(1) of this section may request that its application to be a CAH and a swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved, the approval is effective not earlier than October 1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section, and may not request reinstatement under paragraph (b)(1) of this section.	
C355	(c) Payment. Payment for inpatient RPCH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with §413.70 of this chapter. Payment for post-hospital SNF-level of care services is made in accordance with the payment provisions in §413.114 of this chapter.	
C360	(d) SNF services. The CAH is substantially in compliance with the following SNF requirements contained in Subpart B of part 483 of this chapter:	

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C360 Cont.	(1) Resident rights (§483.10(b)(3) through (b)(6), (d), (e), (h),(i), (j)(1)(vii) and (viii), (1), and (m) of this chapter); (2) Admission, transfer, and discharge rights (§483.12(a) of this chapter); (3) Resident behavior and facility practices (§483.13 of this chapter); (4) Patient activities (§483.15(f) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of §483.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy; (5) Social services (§483.15(g) of this chapter); (6) Comprehensive assessment, comprehensive care plan, and discharge planning (§483.20(b), (d), and (e) of this chapter); (7) Specialized rehabilitative services (§483.45 of this chapter); (8) Dental services (§483.55 of this chapter); (9) Nutrition (§483.25(i) of this chapter).	

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C361	§4**83.10 Residents rights.** The resident has the right to a dignified existence, self determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following: (b) Notice of rights and services. (3) The resident has the right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition.	Interpretive Guideline §483.10(b)(3) "Total health status" includes functional status, medical care, nursing care, nutritional status, rehabilitation and restorative potential, activities potential, cognitive status, oral health status, psychosocial status, and sensory and physical impairments. Information on health status must be presented in language that the resident can understand. This includes minimizing use of technical jargon in communicating with the resident, having the ability to communicate in a foreign language and the use of sign language or other aids, as necessary. (See §483.10(d)(3) Tag C366 for the right of the resident to plan care and treatment). Survey Procedures and Probes §483.10(b)(3) Look, particularly during observations and record reviews, for on-going efforts on the part of facility staff to keep residents informed. Look for evidence that information is communicated in a manner that is understandable to residents and communicated at times it could be most useful to residents, such as when they are expressing concerns, or raising questions, as well as on an on-going basis.
C362	(4) The resident has the right to refuse treatment, to refuse to participate in experimental research, and to formulate an advance directive.	Interpretive Guideline §483.10(b)(4) "Treatment" is defined as care provided for purposes of maintaining/restoring health, improving functional level, or relieving symptoms. "Experimental research" is defined as development and testing of clinical treatments, such as an investigational drug or therapy, that involve treatment and/or control groups. For example, a clinical trial of an investigational drug would be experimental research. "Advance directive" means a written instruction, such as living will or durable power of attorney for health care, recognized under State law relating to the provisions of health care when the individual is incapacitated. As provided under State law, a resident who has the capacity to make a health care decision and who withholds consent to treatment or makes an explicit refusal of treatment either directly or through an advance directive, may not be treated against his/her wishes. A facility may not transfer or discharge a resident for refusing treatment unless the criteria for transfer or discharge are met (See §483.12(a)(1) or (2) (C373 and 374)).

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C362 Cont.		If the resident is unable to make a health care decision, a decision by the resident's surrogate or representative to forego treatment may, subject to State law, be equally binding on the facility. The facility should determine exactly what the resident is refusing and why. To the extent the facility is able, it should address the resident's concern. For example, a resident requires physical therapy to learn to walk again after sustaining a fractured hip. The resident refuses therapy. The facility is expected to assess the reasons for this resident's refusal, clarify and educate the resident as to the consequences of refusal, offer alternative treatments, and continue to provide all other services. If a resident's refusal of treatment brings about a significant change, the facility should reassess the resident and institute care planning changes. A resident's refusal of treatment does not absolve a facility from providing a resident with care that allows him/her to attain or maintain his/her highest practicable physical, mental and psychosocial well being in the context of making that refusal. The resident has the right to refuse to participate in experimental research. A resident being considered for participation in experimental research must be fully informed of the nature of the experiment (e.g., medication, treatment) and understand the possible consequences of participating. The opportunity to refuse to participate in experimental research must occur prior to the start of the research. Aggregated resident statistics that do not identify individual residents may be used for studies without obtaining residents' permission. Survey Procedures and Probes §483.10(b)(4) If the facility participates in any experimental research involving residents, does it have an Institutional Review Board or other committee that reviews and approves research protocols? In this regard, §483.75(c) Relationship to Other HHS Regulations applies (i.e, the facility must adhere to 45 CFR Part 46, Protection of Human Subjects of Research). See §483.10(b)(8) Tag C362 with respect to the advance directives requirement.
C363	(5) The facility must-- (i) Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of--	Interpretive Guideline §483.10(b)(5) and (6) Residents should be told in advance when changes will occur in their bills. Providers must fully inform the resident of services and related changes. "Periodically" means that whenever changes are being introduced that will affect the resident's liability and whenever there are changes in services.

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C363 Cont.	(A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged; (B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and (ii) Inform each resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of this section. (6) The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate.	A Medicare beneficiary who requires services upon admission that are not covered under Medicare may be required to submit a deposit provided that notice provisions of §483.10(b)(6), if applicable, are met. Survey Procedures and Probes §483.10(b)(5) and (6) See §483.10(c)(8) for those items and services that must be included in payment under skilled nursing and nursing facility benefits.
C364	(d) Free Choice. The resident has the right to- (1) Choose a personal attending physician;	Interpretive Guideline §483.10(d)(1) The right to choose a personal physician does not mean that the physician must or will serve the resident, or that a resident must designate a personal physician. If a physician of the resident's choosing fails to fulfill a given requirement, such as §483.25(l)(1), Unnecessary drugs, §483.25(1)(2), Antipsychotic drugs, or §483.40 frequency of physician visits, the facility will have the right, after informing the resident, to seek alternate physician participation to assure provision of appropriate and adequate care and treatment. A facility may not place barriers in the way of residents choosing their own physicians. For example, if a resident does not have a physician, or if the resident's physician becomes unable or unwilling to continue providing care to the resident, the facility must assist the resident in exercising his or her choice in finding another physician.

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C364 Cont.		Before consulting an alternate physician, one mechanism to alleviate a possible problem could involve the facility's utilization of a peer review process for cases which cannot be satisfactorily resolved by discussion between the medical director and the attending physician. Only after a failed attempt to work with the attending physician or mediate differences in delivery of care should the facility request an alternate physician when requested to do so by the resident or when the physician will not adhere to the regulations. If it is a condition for admission to a continuing care retirement center, the requirement for free choice is met if a resident is allowed to choose a personal physician from among those who have practice privileges at the retirement center. A resident in a distinct part of a general acute care hospital can choose his/her own physician, unless the hospital requires that physicians with residents in the distinct part have hospital admitting privileges. If this is so, the resident can choose his/her own physician, but cannot have a physician who does not have hospital admitting privileges. If residents appear to have problems in choosing physicians, determine how the facility makes physician services available to residents.
C365	(2) Be fully informed in advance about care and treatment and of any changes in that care or treatment that may affect the resident's well- being; and	Interpretive Guideline §483.10(d)(2) "Informed in advance" means that the resident receives information necessary to make a health care decision, including information about his/her medical condition and changes in medical condition, about the benefits and reasonable risks of the treatment, and about reasonable available alternatives.
C366	(3) Unless adjudged incompetent or otherwise found to be incapacitated under the laws of the State, participate in planning care and treatment or changes in care and treatment.	Interpretive Guideline §483.10(d)(3) "Participates in planning care and treatment" means that the resident is afforded the opportunity to select from alternative treatments. This applies both to initial decisions about care and treatment and to decisions about changes in care and treatment. The resident's right to participate in care planning and to refuse treatment are covered in §§483.20(d)(2) and 483.10(b)(4). A resident whose ability to make decisions about care and treatment is impaired, or a resident who has been formally declared incompetent by a court, should, to the extent practicable, be kept informed and be consulted on personal preferences.

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C366 Cont.		Whenever there appears to be a conflict between a resident's right and the resident's health or safety, determine if the facility attempted to accommodate both the exercise of the resident's rights and the resident's health, including exploration of care alternatives through a thorough care planning process in which the resident may participate. Survey Procedures and Probes §483.10(d)(3) Look for evidence that the resident was afforded the right to participate in care planning or was consulted about care and treatment changes (e.g., ask residents or their representatives during interviews).
C367	(e) Privacy and confidentiality. The resident has the right to personal privacy and confidentiality for his or her personal and clinical records. (1) Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups, but this does not require the facility to provide a private room for each resident; (2) Except as provided in paragraph (e)(3) of this section, the resident may approve or refuse the release of personal and clinical records to any individual outside the facility; (3) The resident's right to refuse release of personal and clinical records does not apply when-- (i) The resident is transferred to another health care institution; or (ii) Record release is required by law.	Interpretive Guideline §483.10(e) "Right to privacy" means that the resident has the right to privacy with whomever the resident wishes to be private and that this privacy should include full visual, and, to the extent desired for visits or other activities, auditory privacy. Private space may be created flexibly and need not be dedicated solely for visitation purposes. For example, privacy for visitation or meetings might be arranged by using a dining area between meals, a vacant chapel, office or room; or an activities area when activities are not in progress. Arrangements for private space could be accomplished through cooperation between the facility's administration and resident or family groups so that private space is provided for those requesting it without infringement on the rights of other residents. Facility staff must examine and treat residents in a manner that maintains the privacy of their bodies. A resident must be granted privacy when going to the bathroom and in other activities of personal hygiene. If an individual requires assistance, authorized staff should respect the individual's need for privacy. Only authorized staff directly involved in treatment should be present when treatments are given. People not involved in the care of the individual should not be present without the individual's consent while he/she is being examined or treated. Staff should pull privacy curtains, close doors, or otherwise remove residents from public view and provide clothing or draping to prevent unnecessary exposure of body parts during the provision of personal care and services. Personal and clinical records include all types of records the facility might keep on a resident, whether they are medical, social, fund accounts, automated or other. Additional guidelines on mail and visitation are addressed in §483.10(I)(j)(1)(vii) and (viii), (Tag C369 and C370)

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C367 Cont.		Survey Procedures and Probes §483.10(e)(1)-(3) Document any instances where you observe a resident's privacy being violated. Completely document how the resident's privacy was violated (e.g., Resident #12 left without gown or bed covers and unattended), and where and when this occurred (e.g., 2B Corridor, 3:30 p.m. February 25). If possible, identify the responsible party.
C368	(h) Work. The resident has the right to-- (1) Refuse to perform services for the facility; (2) Perform services for the facility, if he or she chooses, when-- (i) The facility has documented the need or desire for work in the plan of care; (ii) The plan specifies the nature of the services performed and whether the services are voluntary or paid; (iii) Compensation for paid services is at or above prevailing rates; and (iv) The resident agrees to the work arrangement described in the plan of care.	Interpretive Guideline §483.10(h)(1)-(2) "Prevailing rate" is the wage paid to workers in the community surrounding the facility for essentially the same type, quality, and quantity of work requiring comparable skills. All resident work, whether of a voluntary or paid nature, must be part of the plan of care. A resident's desire for work is subject to discussion of medical appropriateness. As part of the plan of care, a therapeutic work assignment must be agreed to by the resident. The resident also has the right to refuse such treatment at any time that he or she wishes. At the time of development or review of the plan, voluntary or paid work can be negotiated. Survey Procedures and Probes §483.10(h)(1)-(2) Are residents engaged in what may be paid or volunteer work (e.g., doing housekeeping, doing laundry, preparing meals)? Pay special attention to the possible work activities of residents with mental retardation or mental illness. If you observe such a situation, determine if the resident is in fact performing work and, if so, is this work, whether voluntary or paid, described in the plan of care?
C369	(i) Mail. The resident has the right to privacy in written communications, including the right to-- (1) Send and promptly receive mail that is unopened; and (2) Have access to stationery, postage, and writing implements at the resident's own expense.	Interpretive Guideline §483.10(i)(1)-(2) "Promptly" means delivery of mail or other materials to the resident within 24 hours of delivery by the postal service (including a post office box) and delivery of outgoing mail to the postal service within 24 hours, except when there is no regularly scheduled postal delivery and pickup service.

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C370	(j) Access and Visitation Rights. (1) The resident has the right and the facility must provide immediate access to any resident by the following-- (i) Any representative of the Secretary; (vii) Subject to the resident's right to deny or withdraw consent at any time, immediate family or other relatives of the resident; and (viii) Subject to reasonable restrictions and the resident's right to deny or withdraw consent at any time, others who are visiting with the consent of the resident.	Interpretive Guideline §483.10(j)(1)(I)(vii) and (viii) The facility must provide immediate access to any representative of the Secretary of the Department of Health and Human Services. The residents cannot refuse to see surveyors representing the Department of Health and Human Services. Immediate family or other relatives are not subject to visiting hour limitations or other restrictions not imposed by the resident. However, the facility may try to change the location of visits to assist care giving or protect the privacy of other residents, if these visitation rights infringe upon the rights of other residents in the facility. For example, a resident's family visits in the late evening, which prevents the resident's roommate from sleeping. Non-family visitors must also be granted "immediate access" to the resident. The facility may place reasonable restrictions upon the exercise of this right such as reasonable visitation hours to facilitate care giving for the resident or to protect the privacy of other residents, such as requiring that visits not take place in the resident's room if the roommate is asleep or receiving care. An individual or representative of an agency that provides health, social, legal, or other services to the resident has the right of "reasonable access" to the resident, which means that the facility may establish guidelines regarding the timing or other circumstances of the visit, such as location. These guidelines must allow for ready access of residents to these services. Survey Procedures and Probes §483.10(j)(1)(i)(vii) and (viii) If you identify problems during interviews, determine how the facility ensures access to-- O Representative of the U.S. Department of Health and Human Services (DHHS); O Family or relatives; and O Other visitors.
C371	(l) Personal Property. The resident has the right to retain and use personal possessions, including some furnishings, and appropriate clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.	Interpretive Guideline §483.10(1) All residents' possessions, regardless of their apparent value to others, must be treated with respect, for what they are and for what they may represent to the resident. The right to retain and use personal possessions assures that the residents' environment be as homelike as possible and that residents retain as much control over their lives as possible. The facility has the right to limit the resident's exercise of this right on grounds of space and health or safety.

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C371 Cont.		The intent of this regulation is to encourage residents to bring perrsonal possessions into the facility, as space, safety considerations and fire code permits. Survey Procedures and Probes §483.10(1) If residents' rooms have few personal possessions, ask residents and families if-- O Residents are encouraged to have and to use them; O The facility informs residents not to bring in certain items and for what reason; and O Personal property is safe in the facility. Ask staff if the facility sets limits on the value of the property that residents may have in their possession or requires that residents put personal property in the facility's safe.
C372	(m) Married couples. The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.	Interpretive Guideline §483.10(m) The right of residents who are married to each other to share a room does not give a resident the right, or the facility the responsibility, to compel another resident to relocate to accommodate a spouse. The requirement means that when a room is available for a married couple to share, the facility must permit them to share it if they choose. If a married resident's spouse is admitted to the facility later and the couple want to share a room, the facility must provide a shared room as quickly as posssible. However, a couple is not able to share a room if one of the spouses has a different payment source for which the facility is not certified (if the room is in a distinct part, unless one of the spouses elects to pay for his or her care).
C373	**§483.12 Admission, Transfer, and Discharge Rights.** (a) Transfer and discharge: (1) Definition: Transfer and discharge includes movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not. Transfer and discharge does not refer to movement of a resident to a bed within the same certified facility.	Interpretive Guideline §483.12(a)(1) This requirement applies to transfer or discharges that are initiated by the facility, not by the resident. Whether or not a resident agrees to the facility's decision, these requirements apply whenever a facility initiates the transfer or discharge. "Transfer" is moving the resident from the facility to another legally responsible institutional setting, while "discharge" is moving the resident to a non-institutional setting when the releasing facility ceases to be responsible for the resident's care. Transfer and discharge provisions significantly restrict a facility's ability to transfer or discharge a resident once that resident has been admitted to the facility. The facility may not transfer or discharge the resident unless--

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C373 Cont.		1. The transfer or discharge is necessary to meet the resident's welfare and the resident's welfare cannot be met in the facility; 2. The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility; 3. The safety of individuals in the facility is endangered; 4. The health of individuals in the facility would otherwise be endangered; 5. The resident has failed, after reasonable and appropriate notice, to pay for a stay at the facility; or 6. The facility ceases to operate. To demonstrate that any of the events specified in 1 - 5 have occurred, the law requires documentation in the resident's clinical record. To demonstrate situations 1 and 2, the resident's physician must provide the documentation. In situation 4, the documentation must be provided by any physician. Moreover, before the transfer or discharge occurs, the law requires that the facility notify the resident and, if known, the family member, surrogate, or representative, of the transfer and the reasons for the transfer, and record the reasons in the clinical record. The facility's notice must include an explanation of the right to appeal the transfer to the State as well as the name, address, and phone number of the State long-term care ombudsman. In the case of a developmentally disabled individual, the notice must include the name, address and phone number of the agency responsible for advocating for the developmentally disabled, and in the case of a mentally ill individual, the name, address and phone number of the agency responsible for advocating for mentally ill individuals. See §483.12(a)(4). Generally, this notice must be provided at least 30 days prior to the transfer. Exceptions to the 30-day requirement apply when the transfer is effected because of-- O Endangerment to the health or safety of others in the facility; O When a resident's health has improved to allow a more immediate transfer or discharge; O When a resident's urgent medical needs require more immediate transfer; and O When a resident has not resided in the facility for 30 days. In these cases, the notice must be provided as soon as practicable before the discharge. See §483.12(a)(5).

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C373 Cont.		Finally, the facility is required to provide sufficient preparation and orientation to residents to ensure safe and orderly discharge from the facility. See §483.12(a)(7) Under Medicaid, a participating facility is also required to provide notice to its residents of the facility's bed hold policies and readmission policies prior to transfer of a resident for hospitalization or therapeutic leave. Upon such transfer, the facility must provide written notice to the resident and an immediate family member, surrogate or representative of the duration of any bed-hold. With respect to readmission in a Medicaid participating facility, the facility must develop policies that permit residents eligible for Medicaid, who were transferred for hospitalization or therapeutic leave, and whose absence exceeds the bed-hold period as defined by the State plan, to return to the facility in the first available bed. A resident cannot be transferred for non- payment if he or she has submitted to a third party payor all the paperwork necessary for the bill to be paid. Non-payment would occur if a third party payor, including Medicare or Medicaid, denies the claim and the resident refused to pay for his or her stay.
C374	(2) Transfer and discharge requirements. The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless-- (i) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility; (ii) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility; (iii) The safety of individuals in the facility is endangered; (iv) The health of individuals in the facility would otherwise be endangered;	Interpretive Guideline §483.12(a)(2) and (3) If transfer is due to a significant change in the resident's condition, but not an emergency requiring an immediate transfer, then prior to any action, the facility must conduct the appropriate assessment to determine if a new care plan would allow the facility to meet the resident's needs. (See §483.20(b)(4)(iv) Tag C389 for information concerning assessments upon significant change.) Conversion from a private pay rate to payment at the Medicaid rate does not constitute non-payment. Refusal of treatment would not constitute grounds for transfer, unless the facility is unable to meet the needs of the resident or protect the health and safety of others. Documentation of the transfer/discharge may be completed by a physician extender unless prohibited by State law or facility policy. Survey Procedures and Probes §483.12(a)(2) and (3) During closed record review, determine the reasons for transfer/discharge.

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C375	(v) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge a resident only allowable charges under Medicaid; or (vi) The facility ceases to operate.	O Do records document accurate assessments and attempts through care planning to address the resident's needs through multidisciplinary interventions, accommodation of individual needs and attention to the resident's customary routine? O Did the resident's physician document the record if: The resident was transferred/discharged for the sake of the resident's welfare and the resident's needs could not be met in the facility (e.g., a resident develops an acute condition requiring hospitalization) or The resident's health improved to the extent that the transferred/discharged resident no longer needed the services of the facility. N Did a physician document the record if residents were transferred because the health of individuals in the facility is endangered? O Do the records of residents transferred/discharged due to safety reasons reflect the process by which the facility concluded that in each instance transfer or discharge was necessary? If so, determine differences between these residents and those who were transferred or discharged. O Look for changes in source of payment coinciding with transfer. If you find such transfer, determine if the transfers were triggered by one of the criteria specified in §483.12(a)(2). O If the entity to which the resident was discharged is another long term care facility, evaluate the extent to which the discharge summary and the resident's physician justify why the facility could not meet the needs of this resident.
C376	(3) Documentation. When the facility transfers or discharges a resident under any of the circumstances specified in paragraphs (a)(2)(i) through (v) of this section, the resident's clinical record must be documented. The documentation must be made by-- (i) The resident's physician when transfer or discharge is necessary under paragraph (a)(2)(i) or paragraph (a)(2)(ii) of this section; and (ii) A physician when transfer or discharge is necessary under paragraph (a)(2)(iv) of this section.	

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C377	(4) Notice before transfer. Before a facility transfers or discharges a resident, the facility must-- (i) Notify the resident and, if known, a family member or legal representative of the resident of the transfer or discharge and the reasons for the move in writing and in a language and manner they understand. (ii) Record the reasons in the resident's clinical record; and (iii) Include in the notice the items described in paragraph (a)(6) of this section.	Survey Procedures and Probes §483.12(a)(4)-(6) If the team determines that there are concerns about the facility's transfer and discharge actions, during closed record review, look at notices to determine if the notice requirements are met, including: O Advance notice (either 30 days or, as soon as practicable, depending on the reason for transfer/discharge; O Reason for transfer/discharge; O The effective date of the transfer or discharge; O The location to which the resident was transferred or discharged; and O Right of appeal. Determine whether the facility notified a family member or legal representative of the proposed transfer or discharge.
C378	(5) Timing of the Notice. (I) Except when specified in paragraph (a)(5)(ii) of this section, the notice of transfer or discharge required under paragraph (a)(4) of this section must be made by the facility at least 30 days before the resident is transferred or discharged. (ii) Notice may be made as soon as practicable before transfer or discharge when-- (a) The safety of individuals in the facility would be endangered under paragraph (a)(2)(iii) of this section; (b) The health of individuals in the facility would be endangered, under paragraph (a)(2)(iv) of this section;	

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C378 Cont.	(c) The resident's health improves sufficiently to allow a more immediate transfer or discharge, under paragraph (a)(2)(ii) of this section; (d) An immediate transfer or discharge is required by the resident's urgent medical needs, under paragraph (a)(2)(i) of this section; or (e) A resident has not resided in the facility for 30 days.	
C379	(6) Contents of the Notice. The written notice specified in paragraph (a)(4) of this section must include the following: (i) The reason for transfer or discharge; (ii) The effective date of transfer or discharge; (iii) The location to which the resident is transferred or discharged; (iv) A statement that the resident has the right to appeal the action to the State; (v) The name, address and telephone number of the State long term care ombudsman; (vi) For nursing facility residents with developmental disabilities, the mailing address and telephone number of the agency responsible for the protection and advocacy of developmentally disabled individuals established under Part C of the Developmental	

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C379 Cont.	Disabilities Assistance and Bill of Rights Act; and (vii) For nursing facility residents who are mentally ill, the mailing address and telephone number of the agency responsible for the protection and advocacy of mentally ill individuals established under the Protection and Advocacy for Mentally ill Individuals Act.	
C380	(7) Orientation for transfer or discharge. A facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.	Interpretive Guideline §483.12(a)(7) "Sufficient preparation" means the facility inform the resident where he or she is going and takes steps under its control to assure safe transportation. The facility should actively involve, to the extent possible, the resident and the resident's family in selecting the new residence. Some examples of orientation may include trial visits, if possible, by the resident to a new location; working with family to ask their assistance in assuring the resident that valued possessions are not left behind or lost; orienting staff in the receiving facility to resident's daily patterns; and reviewing with staff routines for handling transfers and discharges in a manner that minimizes unnecessary and avoidable anxiety or depression and recognizes characteristic resident reactions identified by the resident assessment and care plan. Survey Procedures and Probes §483.12(a)(7) During Resident Review, check social service notes to see if appropriate referrals have been made and, if necessary, if resident counseling has occurred.
C381	**§483.13 Resident behavior and facility practices.** .(a) Restraints. The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.	Interpretive Guideline §483.13(a) The intent of this requirement is for each person to reach his/her highest practicable well-being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints. "Physical restraints" are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom of movement or normal access to ones body.

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C381 Cont.		"Chemical Restraint" is defined as a psychopharmacologic drug that is used for discipline or convenience and not required to treat medical symptoms. "Discipline" is defined as any action taken by the facility for the purpose of punishing or penalizing residents. "Convenience" is defined as any action taken by the facility to control resident behavior or maintain residents with a lesser amount of effort by the facility and not in the resident's best interest. Restraint use may constitute an accident hazard and professional standards of practice have eliminated the need for physical restraints except under limited medical circumstances. Therefore, medical symptoms that would warrant the use of restraints should be reflected in the comprehensive assessment and care planning. It is further expected that for those residents whose care plans indicate the need for restraints that the facility engage in a systematic and gradual process toward reducing restraints (e.g., gradually increasing the time for ambulation and muscle strengthening activities). The resident's right to participate in care planning and the right to refuse treatment are addressed at §§483.20(d) and 483.10(b), respectively and include the right to accept or refuse restraints. For the resident to make an informed choice about the use of restraints, the facility should explain to the resident the negative outcomes of restraint use. Potential negative outcomes include incontinence, decreased range of motion, and decreased ability to ambulate, symptoms of withdrawal or depression, or reduced social contact. In the case of a resident who is incapable of making a decision, the surrogate or representative may exercise this right based on the same information that would have been provided to the resident. However, the surrogate or representative cannot give permission to use restraints for the sake of discipline or staff convenience or when the restraint is not necessary to treat the resident's medical symptoms. That is, the facility may not use restraints in violation of the regulation solely because a surrogate or representative has approved or requested them. "Physical restraints" include, but are not limited to, leg restraints, arm restraints, hand mitts, soft ties or vests, lap cushions and lap trays that the resident cannot remove. Also included as restraints are facility practices that meet the definition of a restraint, such as--

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C381 Cont.		o Using bed rails to keep a resident from voluntarily getting out of bed as opposed to enhancing mobility while in bed; o Tucking in a sheet so tightly that a bed bound resident cannot move; o Using wheel chair safety bars to prevent a resident from rising out of a chair; o Placing a resident in a chair that prevents rising; and o Placing a resident who uses a wheelchair so close to a wall that the wall prevents the resident from rising. Orthotic body devices may be used solely for therapeutic purposes to improve overall functional capacity of the resident. Bed rails may be used to restrain residents or to assist in mobility and transfer of residents. The use of bed rails as restraints is prohibited unless they are necessary to treat a resident's medical symptoms. Bed rails used as restraints add risk to the resident. They potentially increase the risk of more significant injury from a fall from a bed with raised bed rails than from a fall from a bed without bed rails. They also potentially increase the likelihood that the resident will spend more time in bed and fall when attempting to transfer from bed. Other interventions that the facility might incorporate in care planning include-- o Providing restorative care to enhance abilities to stand safely and to walk; o A trapeze to increase bed mobility; o Placing the bed lower to the floor and surrounding the bed with a soft mat; o Equipping the resident with a device that monitors attempts to arise; o Providing frequent staff monitoring at night with periodic assisted toileting for residents attempting to arise to use the bathroom; and/or o Furnishing visual and verbal reminders to use the call bell for residents who are able to comprehend this information. When used for mobility or transfer, assessment should include a review of the residents-- o Bed mobility (e.g., would the use of the bed rail assist the resident to turn from side to side? Or, is the resident totally immobile and cannot shift without assistance?); and o Ability to transfer between positions, to and from bed or chair, to stand and toilet (e.g., does the raised bed rail add risk to the resident's ability to transfer?). However, as with other restraints, for residents who have been restrained by bed rails, it is expected that the process facilities employ to reduce the use of bed rails as restraints is systematic and gradual (e.g., lessening the time the bed rail is used while increasing visual and verbal reminders to use the call bell).

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C381 Cont.		Before a resident is restrained, the facility must demonstrate the presence of a specific medical symptom that would require the use of restraints, and how the use of restraints would treat the cause of the symptom and assist the resident in reaching his or her highest level of physical and psychosocial well-being. Appropriate exercise, therapeutic interventions such as orthotic devices, pillows, pads, or lap trays often assist in achieving proper body position, balance and alignment, without the potential negative effects associated with restraint use. Restraints may not be used to permit staff to administer treatment to which the resident has not consented. However, if the resident needs emergency care, restraints may be use for brief periods to permit medical treatment to proceed unless the facility has a notice indicating that the resident has previously made a valid refusal of the treatment in question. Survey Procedures an d Probes §483.13(a) Since continued restraint usage is associated with a potential for a decline in functioning if the risk is Not addressed, determine if the interdisciplinary team addressed the risk of decline at the time restraint Use was initiated and that the care plan reflected measures to minimize a decline. Also determine if the plan of care was consistently implemented. Determine whether the decline can be attributable to unavoidable disease progression, versus inappropriate use of restraints. Determine if the facility follows a systematic process of evaluation and care planning prior to using restraints. For sampled residents observed as physically restrained during the survey or whose clinical Records show the use of physical restraints within 30 days of the survey, determine the intended use of the restraint, convenience or discipline, or a therapeutic intervention for specified periods to attain and maintain the resident's highest practicable physical, mental or psychosocial well being. This systematic process should answer these questions-- 1. What are the symptoms that led to the consideration of the use of restraints? 2. Are these symptoms caused by failure to-- o Meet individual needs in accordance with section III of the M.D.S., Customary Daily Routines (M.D.S. version 2.0 section AC), in the context of relevant information in sections I and II of the M.D.S. (M.D.S. version 2.0 sections AA and AB)? o Use aggressive rehabilitative/restorative care? o Provide meaningful activities? o Manipulate the resident's environment, including seating?

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C381 Cont.		3. Can the cause(s) be removed? 4. If the cause(s) cannot be removed, then has the facility attempted to use alternatives in order to avoid a decline in physical functioning associated with restraint use? (See Physical Restraints Resident Assessment Protocol (RAP), paragraph 1). 5. If the alternatives have been tried and found wanting, does the facility use the least restrictive restraint for the least amount of time? Does the facility monitor and adjust care to reduce negative outcomes while continually trying to find and use less restrictive alternatives? 6. Did the resident make an informed choice about the use of restraints? Were risks, benefits, and alternatives explained? 7. Does the facility use the Physical Restraints RAP to evaluate the appropriateness of restraint use? 8. Has the facility re-evaluated the need for the restraint, made efforts to eliminate its use and maintained resident's strength and mobility? If responses to these questions indicate that restraint use may not comply with these requirements, is there evidence of restraints used for staff convenience (i.e., restrained residents left alone for lone periods, not toileted and not provided with exercise. Refer to M.D.S. sections Customary Daily Routine, K, N, E, H, L, (M.D.S. version 2.0 sections AC, J, M, G, E and K respectively) and relevant RAPS, and to notes from other health professionals to determine if restrained residents have maintained their physical, mental, psychosocial and functional status; or if the use of restraints has been associated with an increase in falls, urinary or fecal incontinence, pressure sores, loss of muscle tone, loss of independent mobility, increased agitation, loss of balance, symptoms of withdrawal or depression, reduced social contact, or decreased appetite.
C382	(b) Abuse. The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.	Interpretive Guideline §483.13(b)(c) These requirements specify the right of each resident to be free from abuse, corporal punishment, and involuntary seclusion, and the facility's responsibilities to prevent not only abuse, but also those practices and omissions, neglect and misappropriation of property, that if left unchecked, lead to abuse.

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C382 Cont.		Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the individual, family members or legal guardians, friends, or other individuals. "Abuse" is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm or pain or mental anguish, or deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well being. This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish. "Verbal abuse" is defined as any use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. Examples of verbal abuse include, but are not limited to: threats of harm; and saying things to frighten a resident, such as telling a resident that she will never be able to see her family again. "Sexual abuse" includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault. "Physical abuse" includes hitting, slapping, pinching and kicking. It also includes controlling behavior through corporal punishment. "Mental abuse" includes, but is not limited to, humiliation, harassment, threats of punishment or deprivation. "Involuntary seclusion" is defined as separation of a resident from other residents or from his or her room or confinement to his or her room (with or without roommates) against the resident's will, or the will of the resident's legal representative. Emergency or short term monitored separation from other residents will not be considered involuntary seclusion and may be permitted if used for a limited period of time as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident's needs. <u>Survey Procedures and Probes §483.13(b)</u> Offsite, presurvey review of complaints can focus the survey team's on-site review of actual incidents and predisposing factors to abuse or neglect and misappropriation of property.

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C382 Cont.		Report and record any instances where the survey team observes an abusive incident. Completely document who committed the abusive act, the nature of the abuse, and where and when it occurred. Ensure that the facility addresses that incident immediately. If the survey team's observations and resident's responses signal the presence of abuse, determine how the facility prevents and reports abusive behavior as described in §483.13(c). If a resident is being temporarily separated from other residents, i.e., for less than 24 hours, as an emergency short-term intervention, answer these questions-- 1. What are the symptoms that led to the consideration of the separation? 2. Are these symptoms caused by failure to-- o Meet individual needs in accordance with section III (M.D.S. version 2.0 section AC), Customary Daily Routines, in the context of relevant information in sections I (M.D.S. and II of the M.D.S. (M.D.S. version 2.0 sections AA and AB)? o Provide meaningful activities? o Manipulate the resident's environment? 3. Can the cause(s) be removed? 4. If the cause(s) cannot be removed, has the facility attempted to use alternatives short of separation? 5. If these alternatives have been tried and found wanting, does the facility use the separation for the least amount of time? 6. To what extent has the resident, surrogate or representative participated in care planning and made an informed choice about separation? 7. Does the facility monitor and adjust care to reduce negative outcomes, while continually trying to find and use less restrictive alternatives? 8. If residents are temporarily separated in secured units, staff should carry keys to these units at all times. 9. If the purpose of the unit is to provide specialized care for residents who are cognitively impaired (through a program of therapeutic activities designed to enable residents to attain and maintain the highest practicable physical, mental or psychosocial well-being) then placement in the unit is not in violation of resident rights, as long as the resident's individual care plan indicates the need for the stated purpose and services provided in the unit and the resident, surrogate, or representative has participated in the placement decision.

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C382 Cont.		10. If the purpose of the unit is to provide an emergency short term monitored separation for a resident who showed temporary behavior problems (such as brief catastrophic reactions or combative or aggressive behaviors which pose a threat to the resident, other residents, staff or others in the facility) then answer the questions with regard to temporary separation set out above.
C383	(c) Staff treatment of residents. The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property. (1) The facility must-- (i) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;	Interpretive Guideline §483.13(c) The intent of this regulation is to assure that the facility has in place an effective system that regardless of the source (staff, other residents, visitors, etc), prevents mistreatment, neglect and abuse of residents, and misappropriation of resident's property. However, such a system cannot guarantee that a resident will not be abused; it can only assure that the facility does whatever is within its control to prevent mistreatment, neglect, and abuse of residents or misappropriation of their property. Such steps include, but are not limited to, identification of residents whose personal histories render them at risk for abusing other residents, an assessment of appropriate intervention strategies to prevent occurrences, monitoring the resident for any changes that would trigger abusive behavior, and reassessment of the strategies on a regular basis. For each sampled resident in a secured unit, determine the facility's stated purpose for the unit and the facility's intent in placing the individual in the unit. "Neglect", is defined as failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. (See Older Americans Act, §302(a)(29)). Neglect occurs on an individual basis when a resident has a lack of care in one or more areas (e.g., absence of frequent monitoring for a resident known to be incontinent, resulting in being left to lie in urine or feces). "Misappropriation of resident property" is defined as the patterned or deliberate misplacement, exploitation, or wrongful, temporary or permanent use of a resident's belongings or money without the resident's consent.
C384	(ii) Not employ individuals who have been-- (A) Found guilty of abusing, neglecting, or mistreating residents by a court of law; or	Interpretive Guideline §483.13(c)(1)(ii) The intent of this regulation is to prevent employment of individuals who have been convicted of abusing, neglecting, or mistreating individuals in a health care related setting (e.g., residents of a nursing facility or patients in a hospital). Facilities must be thorough in their investigations of the past

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C384 Cont.	(B) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and (iii) Report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff to the State nurse aide registry or licensing authorities. (2) The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency). (3) The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress. (4) The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.	Histories of individuals they are considering hiring. In addition to inquiry of the State nurse aide registry or other licensing authorities, the facility should check all references and make reasonable efforts to uncover information about any past criminal prosecutions. "Found guilty...by a court of law" applies to situations where the defendant pleads guilty, is found guilty, or pleads nolo contendere. "Finding" is defined as a determination made by the State that validates allegations of abuse, neglect, mistreatment of residents or misappropriation of their property. Interpretive Guidelines §483.13(c)(1)(iii) An aide or other facility staff found guilty of neglect, abuse, or mistreating residents or misappropriation of property by a court of law, must have his or her name entered into the nurse aide registry, or reported to the licensing authority, if applicable. Further, if a facility determines that actions by a court of law against an employee are such that they indicate that the individual is unsuited to work in a nursing home (e.g., felony conviction of child abuse, sexual assault, or assault with a deadly weapon), then the facility must report that individual to the nurse aide registry (if a nurse aide) or to the State licensing authority (if a licensed staff member). Such a determination by the facility is not limited to mistreatment, neglect and abuse of residents and misappropriation of their property, but to any treatment of residents or others inside or outside the facility which the facility determines to be such that the individual should not work in a nursing home environment. If, during a survey, the survey team is made aware of a previous incident of neglect or abuse, evaluate current residents for evidence of similar problems that might indicate that the facility has not addressed systemic problems to protect residents from neglect, abuse and misappropriation of property. Survey Procedures and Probes §483.13(c)(2)(3) and (4) During Sample Selection-- 1. If the team has identified a problem in mistreatment, neglect or abuse of residents or misappropriation of their property, then request--

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C384 Cont.		o A copy of the facility's policies and procedures regarding abuse prevention: note particularly the extent to which those policies concern the areas uncovered through complaints and/or previous survey; o Reports of action(s) by a court of law against employees; o Reports of alleged violations involving mistreatment, neglect, abuse, injuries of unknown source, and misappropriation of resident's property; o Reports of the results of these investigations; and o Records of corrective actions taken. 2. In addition, spot check employment-- o Applications for questions about convictions or mistreatment, neglect or abuse of residents, or misappropriation of their property. Determine if applicants have answered these questions and if affirmative answers had resulted in rejections of employment candidates. o Records for contact with State Nurse Aide Registry. Determine if applicants with a finding concerning mistreatment, neglect, abuse of residents or misappropriation of their property have been rejected. o New employees for registry entries. 3. Ask for the results of any in-house investigations of mistreatment, neglect, or abuse of residents, misappropriation of their property, or injuries of unknown sources. o Was the administrator notified of the incident and when? o Did investigations begin promptly after the report of the problem? o Is there a record of statements or interviews of the resident, suspect (if one is identified), any eye witnesses and any circumstantial witnesses? o Was relevant documentation reviewed and preserved (e.g., dated dressing which was not changed when treatment recorded change)? o Was the alleged victim examined promptly (if injury was suspected) and the finding documented in the report? o What steps were taken to protect the alleged victim from further abuse (particularly where no suspect has been identified?) o What actions were taken as a result of the investigation? o What corrective action was taken, including informing the nurse aide registry, State licensure authorities, and other agencies (e.g., long-term care ombudsman; adult protective services; Medicaid fraud and abuse unit)?

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C385	**§483.15 Quality of Life.** A facility must care for its residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life. (f) Activities. (1) The facility must provide for an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interests and the physical, mental, and psychosocial well-being of each resident. (2) The activities program must be directed by a qualified professional who-- (i) Is a qualified therapeutic recreation specialist or an activities professional who-- (A) Is licensed or registered, if applicable, by the State in which practicing; and (B) Is eligible for certification as a therapeutic recreation specialist or as an activities professional by a recognized accrediting body on or after October 1, 1990; or (ii) Has 2 years of experience in a social or recreational program within the last 5 years, 1 of which was full-time in a patient activities program in a health care setting; or	Interpretive Guidelines §483.15(f)(1) Because the activities program should occur within the context of each resident's comprehensive assessment and care plan, it should be multi-faceted and reflect each individual resident's needs. Therefore, the activities program should provide stimulation or solace; promote physical, cognitive and/or emotional health; enhance, to the extent practicable, each resident's physical and mental status; and promote each resident's self-respect by providing, for example, activities that support self-expression and choice. Activities can occur at anytime and are not limited to formal activities being provided by activity staff. Others involved may be any facility staff, volunteers and visitors. Survey Procedures and Probes §483.15(f)(1) Observe individual, group and bedside activities. 1. Are residents who are confined or choose to remain in their rooms provided with in room activities in keeping with lifelong interests (e.g., music, reading, visits with individuals who share their interests or reasonable attempts to connect the resident with such individuals) and in room projects they can work on independently? Do any facility staff members assist the resident with activities he or she can pursue independently? 2. If residents sit for long periods of time with no apparently meaningful activities, is the cause-- o Resident choice; o Failure of any staff or volunteers either to inform residents when activities are occurring or to encourage resident involvement in activities; o Lack of assistance with ambulation; o Lack of sufficient supplies and/or staff to facilitate attendance and participation in the activity programs; or o Program design that fails to reflect the interests or ability levels of residents, such as activities that are too complex? For residents selected for a comprehensive review, or a focused review, as appropriate, determine to what extent the activities reflect the individual resident's assessment. (See especially M.D.S. III.1 and Sections B, C, D, and I; M.D.S. version 2.0 sections AC, B, C, D, and N.)

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C385 Cont.	(iii) Is a qualified occupational therapist or occupational therapy assistant; or (iv) Has completed a training course approved by the State.	Review the activity calendar for the month prior to the survey to determine if the formal activity program: o Reflects the schedules, choices and rights of the residents; o Offers activities at hours convenient to the residents (e.g., morning, afternoon, some evenings and weekends); o Reflects the cultural and religious interests of the resident population; and o Would appeal to both men and women and all age groups living in the facility. Review clinical records and activity attendance records of residents receiving a comprehensive review, or a focused review, as appropriate, to determine if-- o Activities reflect individual resident history indicated by the comprehensive assessment; o Care plans address activities that are appropriate for each resident based on the comprehensive assessment; o Activities occur as planned; and o Outcomes/responses to activities interventions are identified in the progress notes of each resident. Interpretive Guideline §483.15(f)(2) A "recognized accrediting body" refers to those organizations or associations recognized as such by certified therapeutic recreation specialists or certified activity professionals or registered occupational therapists. Survey Procedures and Probes §483.15(f)(2) If there are problems with provision of activities, determine if these services are provided by qualified staff.

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C386	(g) Social Services. (1) The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. NOTE: §483.15(g)(2) which requires a full time qualified social worker be employed is inapplicable to CAHs.	Interpretive Guideline §483.15(g)(1) Regardless of size, all facilities are required to provide for the medically related social services needs of each resident. This requirement specifies that facilities aggressively identify the need for medically-related social services, and pursue the provision of these services. It is not required that a qualified social worker necessarily provide all of these services. Rather, it is the responsibility of the facility to identify the medically-related social service needs of the resident and assure that the needs are met by the appropriate discipline. The intent is to assure that sufficient and appropriate social services are provided to meet the resident's needs. "Medically -related social services" means services provided by the facility's staff to assist residents in maintaining or improving their ability to manage their everyday physical, mental, and psychosocial needs. These services might include, for example-- o Making arrangements for obtaining needed adaptive equipment, clothing, and personal items; o Maintaining contact with family (with resident's permission) to report on changes in health, current goals, discharge planning, and encouragement to participate in care planning; o Assisting staff to inform residents and those they designate about the resident's health status and health care choices and their ramifications; o Making referrals and obtaining services from outside entities (e.g., talking books, absentee ballots, community wheelchair transportation); o Assisting residents with financial and legal matters (e.g., applying for pensions, referrals to lawyers, referrals to funeral homes for preplanning arrangements); o Discharge planning services (e.g., helping to place a resident on a waiting list for community congregate living, arranging intake for home care services for residents returning home, assisting with transfer arrangements to other facilities); o Providing or arranging provision of needed counseling services; o Through the assessment and care planning process, identifying and seeking ways to support residents' individual needs and preferences, customary routines, concerns and choices; o Building relationships between residents and staff and teaching staff how to understand and support residents individual needs; o Promoting actions by staff that maintain or enhance each resident's dignity in full recognition of each resident's individuality; o Assisting residents to determine how they would like to make decisions about their health care, and whether or not they would like anyone else to be involved in those decisions; o Finding options that most meet the physical and emotional needs of each resident;

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C386 Cont.		o Providing alternatives to drug therapy or restraints by understanding and communicating to staff Why residents act as they do, what they are attempting to communicate, and what needs the staff must meet; o Meeting the needs of residents who are grieving; and o Finding options which most meet their physical and emotional needs. Factors with a potentially negative effect on physical, mental, and psychosocial well-being include an unmet need for: o Dental/denture care; o Podiatric care; o Eye care; o Hearing services; o Equipment for mobility or assistive eating devices; and o Need for home-like environment, control, dignity, privacy. Where needed services are not covered by the Medicaid State Plan, nursing facilities are still required to attempt to obtain these services. For example, if a resident requires transportation services that are not covered under a Medicaid State Plan, the facility is required to arrange these services. This could be achieved, for example, through obtaining volunteer assistance. Types of conditions to which the facility should respond with social services by staff or referral include: o Lack of an effective family/social support system; o Behavioral symptoms; o If a resident with dementia strikes out at another resident, the facility should evaluate the resident's behavior. For example, a resident may be re-enacting an activity he or she used to perform at the same time everyday. If that resident senses that another is in the way of his or her re-enactment, the resident may strike out at the resident impeding his or her progress. The facility is responsible for the safety of any potential resident victim while it assesses the circumstances of the resident's behavior); o Presence of a chronic disabling medical or psychological condition (e.g., multiple sclerosis, chronic obstructive pulmonary disease, Alzheimer's disease, schizophrenia); o Depression; o Chronic or acute pain; o Difficulty with personal interaction and socialization skills; o Presence of legal or financial problems; o Abuse of alcohol or other drugs;

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C386 Cont.		o Inability to cope with loss of function; o Need for emotional support; o Changes in family relationships, living arrangements, and/or resident's condition or functioning; and o A physical or chemical restraint. For residents with or who develop mental disorders as defined by The Diagnostic and Statistical Manual for Mental Disorders (DSM-IV), see §483.45 Tag C401. Survey Procedures and Probes §483.15(g)(1) For residents selected for a comprehensive or focused review as appropriate-- o How do facility staff implement social services interventions to assist the resident in meeting treatment goals? o How do staff responsible for social work monitor the resident's progress in improving physical, mental and psychosocial functioning? Has goal attainment been evaluated and the care plan changed accordingly? o How does the care plan link goals to psychosocial functioning/well being? o Have the staff responsible for social work established and maintained relationships with the resident's family or legal representative? o What attempts does the facility make to access services for Medicaid recipients when those services are not covered by a Medicaid State Plan? Look for evidence that social services interventions successfully address residents' needs and link social supports, physical care, and physical environment with residents' needs and individuality .
C388	**§483.20 Resident assessment.** The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity.	Interpretive Guidelines §483.20(b)(1)(2) The guidelines for resident assessment are consistent with the requirements for each State's specified Resident Assessment Instrument (RAI). The assessments provide the facility with the information necessary to develop a care plan and to provide the appropriate care and services for each resident. Each State's RAI includes at least the Minimum Data Set (M.D.S.) and common definitions, triggers, and utilization guidelines developed by HCFA, which include the Resident Assessment Protocols (RAPS).

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C388 Cont.	(b) Comprehensive assessment. (1) The facility must make a comprehensive assessment of a resident's needs which-- (i) Is based on a uniform data set specified by the Secretary and uses an instrument that is specified by the State and approved by the Secretary; and (ii) Describes the resident's capability to perform daily life functions and significant impairments in functional capacity. (2) The comprehensive assessment must include at least the following information-- (i) Medically defined conditions and prior medical history; (ii) Medical status measurement; (iii) Physical and mental functional status;	The information required in §483.20(b)(2)(I - xiii) is incorporated into the MDS, which forms the core of each States's approved RAI. Additional assessment information is also gathered using triggered RAPS. Each facility must use its State specified RAI (which includes both the MDS and utilization guidelines including the RAPs) to assess newly admitted residents, annual review and those residents who experience a significant change in status. The facility is responsible for addressing all needs and strengths of residents regardless of whether the issue is included in the MDS or RAPS. The scope of the RAI does not limit the facility's responsibility to assess and address all care needed by the resident. Furthermore, the facility is responsible for addressing the resident's needs from the moment of admission. All reference to version 2.0 (v. 2.0) of the MDS are effective when the State respecifies its RAI. (This corresponds to MDS Identification Information I.11-12 and Section J; MDS v. 2.0 Section AB9-10 and Section I, Disease Diagnosis, respectively.) "Medically defined conditions and prior medical history" is defined as the resident's medical history before admission and a description of current medical diagnoses. It includes history of mental retardation and current mental illness, if applicable. (This corresponds to MDS section B1-6, J1-2, K1 and K3, and P1-2; MDS v. 2.0 sections B1-6, I1-2, J1-3, 5 and P1 and 9.) "Medical status measurement" is defined as objective measurements of a resident's physical and mental abilities including, but not limited to, information on vital signs, clinical laboratory values, or diagnostic test. (This corresponds to MDS sections E1-8 and G1-3; MDS v. 2.0 sections G1-9 and F1-3.) "Physical and mental functional status" is defined as the resident's ability to perform activities of daily living including bathing, dressing and grooming, transferring and ambulating, toilet use, eating, and using speech, language, or other communication systems. Includes determining the resident's need for staff assistance and assistive devices or equipment to maintain or improve functional abilities and the resident's ability to form relationships, make decisions including health care decisions, and participate (to the extent physically able) in the day to day activities of the facility.

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C388 Cont.	(iv) Sensory and physical impairments;	(This corresponds to MDS sections C1-6, D1-3, E4 and F1-4; MDS v. 2.0 sections C1-7, D1-3, G4, and H1-4.) "Sensory and physical impairments" are defined as neurological or muscular deficits. For example, a decrease in vision or hearing, paralysis, or bladder incontinence.
	(v) Nutritional status and requirements;	(This corresponds to MDS section L1-4; MDS v. 2.0 section K1-6.) "Nutritional status and requirements" are defined as weight, height, hematologic and biochemical assessments, clinical observations of nutrition, nutritional intake, resident's eating habits and preferences, and dietary restrictions.
	(vi) Special treatments or procedures;	(This corresponds to MDS sections L4, N1-4, P1; MDS v. 2.0 sections K5, M5, and P1.) "Special treatments or procedures" are defined as treatments and procedures that are <u>not</u> part of basic services provided. For example, treatment for pressure sores, nasogastric feedings, specialized rehabilitation services, or respiratory care.
	(vii) Mental and psychosocial status;	(This corresponds to MDS sections III (customary routine), G1-3 and H; MDS v. 2.0 sections AC, F1-3, and E.) "Mental and psychosocial status" is defined as the resident's ability to deal with life, interpersonal relationships and goals, make health care decisions, and indicators of resident behavior and mood.
	(viii)Discharge potential;	(This corresponds to MDS section A10; v. 2.0 section Q.) "Discharge potential" is defined as the facility's expectation of discharging the resident from the facility within the next three months.
	(ix) Dental condition;	(This corresponds to MDS section M; MDS v. 2.0 section L.) "Dental condition" is defined as the condition of the teeth, gums, and other structures of the oral cavity that may affect a resident's nutritional status, communication abilities, or quality of life. The assessment should include the need for, and use of, dentures or other dental appliances.
	(x) Activities potential;	(This corresponds to M.D.S. section I (activities pursuit) and III (customary routine); M.D.S. v. 2.0 section N and AC.) "Activities potential" is defined as the resident's ability and desire to take part in activities which maintain or improve, physical, mental, and psychosocial well-being. Activity pursuits refer to any activity outside of activities of daily living (ADLs) which a person pursues in order to obtain a sense of well-being. Also, includes activities which provide benefits in self-esteem, pleasure, comfort, health education, creativity, success, and financial or emotional independence. The assessment should consider the resident's normal everyday routines and lifetime preferences.

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C388 Cont.	(xi) Rehabilitation potential; (xii) Cognitive status; and (xiii) Drug therapy.	(This corresponds to MDS section E7; MDS v. 2.0 section G8.) "Rehabilitation potential" is defined as the ability to improve independence in functional status through restorative care programs. (This corresponds to MDS section B1-6; MDS v. 2.0 section B1-6) OCognitive statuso is defined as the resident's ability to problem solve; decide, remember, and be aware of and respond to safety hazards. (This corresponds to MDS section O; v. 2.0 section O.) ODrug therapy" is defines as all prescription and over-the-counter medications taken by the resident, including dosage, frequency of administration, and recognition of significant side effects that would be most likely to occur in the resident. This information need not appear in the assessment. However, it must be in the resident's clinical record and included in the care plan. Survey Procedures and Probes: §483.20(b)(1)(2) O Has each resident in the sample been comprehensively assessed using the State specified RAI within the regulatory timeframes (i.e., within 14 days of admission, on significant change in status, and at least annually)? O Has the facility gathered supplemental assessment information based on triggered RAPs prior to establishing the care plan? O Does information in the RAI correspond with information obtained during observations of and interviews with the resident, facility staff and resident's family?
C389	(4) Frequency. Assessments must be conducted-- (i) No later than 14 days after the date of admission; (ii) For current NF residents not later than October 1, 1991; (iii) For current SNF residents, not later than January 1, 1991; Item (ii) does not apply to CAHs.	Interpretive Guidelines §483.20(b)(4) The intent of this regulation is to assess residents in a timely manner. "Admission to the facility is defined as an initial stay or a return stay (not a readmission) in the facility. A return stay applies to those residents who are discharged without expectation that they will return to the facility, but who do return to the facility. A "readmission is an expected return to the facility following a temporary absence for hospitalization, off-site visit or therapeutic leave. A resident who is readmitted and for whom there is a prior RAI on file does not require a new assessment unless a significant change in status has occurred (see below), and should remain on the same schedule as if there had been no temporary absence. An M.D.S./RAI need not be completed for residents discharged in less than 14 days, although the facility is to provide care appropriate to the resident's needs from admission to discharge.

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C390	(iv) Promptly after a significant change in the resident's physical or mental condition; and	If the resident experiences a significant change in status, the next annual assessment is not due until 365 days after the significant change reassessment. Facilities may correct errors on the M.D.S. per HCFA policy within 7 days of its completion. The following guidance concerning significant change is applicable until the State respecifies its RAI for version 2.0. A "significant change" may include, but is not limited to, any of the following, or may be determined by a physician's decision if uncertainty exists-- o Deterioration in two or more ADLs, or any combination of deterioration in two or more areas of ADLs, communication, or cognitive abilities that appear permanent. For example, pronounced deterioration in function and communication following a stroke; o Loss of ability to ambulate freely or to use hands to grasp small objects to feed or groom oneself, such as spoon, toothbrush or comb. Temporary loss of ability, such as during an acute illness, is not included; o Deterioration in behavior or mood, to the point where daily problems arise or relationships have become problematic and staff conclude that these changes in the resident's psychosocial status are not likely to improve without staff intervention; o Deterioration in a resident's health status, where this change places the resident's life in danger, (e.g., stroke, heart disease, metastatic cancer); is associated with a serious clinical complication (e.g., initial development of a stage III pressure sore, prolonged delirious state, or recurrent decline in level of consciousness); or is associated with an initial diagnosis of a condition that is likely to affect the resident's physical, mental, or psychosocial well-being over a prolonged period of time, (e.g., Alzheimer's disease or diabetes) or the onset of significant (unplanned) weight loss (5% in last 30 days, 10% in last 180 days); or o Improvement in behavior, mood or functional status to the extent that the plan of care no longer addresses the needs of the resident. Comprehensive resident assessment is not required if declines in physical, mental or psychosocial well being are short-term or insignificant (i.e., do not require a change in the resident's care plan). This may include-- o Discrete and easily reversible symptoms documented in the resident's record and for which facility staff can initiate corrective action. For example, an anticipated side effect of introducing a psychotropic medication while attempting to establish a clinically effective dose level;

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C390 Cont.		" Short-term acute illness such as a mild fever secondary to a cold from which facility staff expect a full recovery of the resident's pre-morbid functional abilities and health status; o Well established symptoms associated with previously diagnosed cyclical conditions. For example, depressive symptoms in a resident previously diagnosed with bipolar disease; or o If the resident continues to make steady progress under the current course of care, reassessment is required only when the condition has stabilized. "Promptly" means that once it is determined that the resident's change in status is significant or likely to be permanent, a full assessment must be completed within 14 days of this determination. The following definition of a criteria for significant change are effective when the State respecifies its RAI-- A "significant change" is a major change in the resident's status that is not self-limiting, impacts on more than one area of the resident's health status, and requires interdisciplinary review and/or revision of the care plan. According to this definition, a significant change reassessment would be indicated if decline or improvement is consistently noted in 2 or more areas of decline or 2 or more areas of improvement. Following are examples which could indicate a significant change. <u>Decline:</u> o Any decline in ADL physical functioning where a resident is newly coded as 3, 4 or 8 (Extensive assistance, Total dependency, Activity did not occur); o Increase in the number of areas where Behavioral Symptoms are coded as "not easily altered" (i.e., an increase in the number of code "1's" for E4B); o Resident's decision making changes from 0 or 1, to 2 or 3; o Resident's incontinence pattern changes from 0 or 1 to 2, 3 or 4, or placement of an indwelling catheter; o Emergence of sad or anxious mood as a problem that is not easily altered; o Emergence of an unplanned weight loss problem (5% change in 30 days or 10% change in 180 days); o Begin to use trunk restraint or a chair that prevents rising for a resident when it was not used before; o Emergence of a condition/disease in which a resident is judged to be unstable; o Emergence of a pressure ulcer at stage II or higher, when no ulcers were previously present at Stage II or higher; or o Overall deterioration of resident's condition; resident received more support (e.g., in ADLs or decision making).

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C390 Cont.		Improvement: o Any improvement in ADL physical functioning where a resident is newly coded as 0, 1, or 2 when previously scored as a 3, 4, or 8; o Decrease in the number of areas where Behavioral Symptoms or Sad or Anxious Mood are coded as "not easily altered"; o Resident's decision making changes from 2 or 3, to 0 or 1; o Resident's incontinence pattern changes from 2, 3, or 4 to 0 or 1; or o Overall improvement of resident's condition; resident receives fewer supports. If the resident experiences a significant change in status, the next annual assessment is not due until 365 days after the significant change reassessment. Survey Procedures and Probes: §483.20(b)(4) o Has each resident in the sample been comprehensively assessed using the State-specified RAI within the regulatory timeframes (i.e., within 14 days after admission, on significant change in status, and at least annually)? o Has the facility identified those residents who have experienced a significant change? o Has the facility reassessed residents using the State-specified RAI who had a change in status within 14 days after determining the change was significant or appears to be permanent?
C391	(v) In no case less often than once every 12 months.	
C392	(5) Review of Assessments. The nursing facility must examine each resident no less than once every 3 months, and as appropriate, revise the resident's assessment to assure the continued accuracy of the assessment.	Interpretive Guidelines: §483.20(b)(5) The intent of the regulation is to assure that the resident's assessment is accurate and reflects the resident's current status. At least each quarter, the facility shall review each resident with respect to those M.D.S. items specified under the State's quarterly review requirement. At a minimum, this would include all items contained in HCFA's quarterly review form. Until the State respecifies its RAI for version 2.0, facilities are not required to use HCFA's form unless specified by the State. However, when the State respecifies its RAI, the quarterly review form will be required. If the resident has experienced a significant change in status, the next quarterly review is due no later than 3 months after the significant change reassessment. Until the State respecifies its RAI, review at least quarterly;

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C392 Cont.		o Cognitive patterns, especially memory and daily decision-making ability; o Communication/hearing ability, especially the ability to make ones self understood and to understand others; o Physical functioning and ADL abilities; o Continence; o Mood and behavior patterns; o New disease diagnoses that have a relationship to current ADL status, behavior status, medical treatments, or risk of death; o Weight loss; o Medication use, particularly psychotropic medications; and o Special treatments and procedures, including restraints. NOTE: These quarterly assessment domains will no longer apply when the State respecifies its RAI. Survey Procedures and Probes: §483.20(b)(5) o Is the facility assessing and acting, no less than once every 3 months, on the results of resident's functional and cognitive status examinations? o Is the quarterly review of the resident's condition consistent with information in the progress notes, the plan of care and your resident observations and interviews?
C393	(6) Use. The results of the assessment are used to develop, review, and revise the resident's comprehensive plan of care, under paragraph (d) of this section.	Survey Procedures and Probes: §483.20(b)(6) See §483.20(d).
C394	(7) Coordination. The facility must coordinate assessments with any State-required preadmission screening program to the maximum extent practicable to avoid duplicative testing and effort.	Interpretive Guidelines: §483.20(b)(7) As the facility determines appropriate, if required portions of the comprehensive assessment have been performed as part of a pre-admission screening program, enter the results of the pre-admission screening into the appropriate portion of the comprehensive assessment instrument. Unless a significant change has occurred between pre-admission screening and admission, the facility may choose not to repeat those portions of the assessment. For example, medical records containing the resident's history and course of previous hospitalizations, pertinent laboratory results and social history data may be used where applicable to enter information on the assessment form. The intent of this regulation is to prevent duplicative data gathering by using M.D.S. assessment Information for more than one purpose.

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C395	(d) Comprehensive care plans. (1) The facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, mental and psychosocial needs that are identified in the comprehensive assessment. The care plan must describe the following-- (i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.25; and (ii) Any services that would otherwise be required under §483.25 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(b)(4).	Interpretive Guidelines: §483.20(d) An interdisciplinary team, in conjunction with the resident, resident's family, surrogate, or representative, as appropriate, should develop quantifiable objectives for the highest level of functioning the resident may be expected to attain, based on the comprehensive assessment. The interdisciplinary team should show evidence in the RAP Summary or clinical record of the resident's status in triggered RAP areas and their rationale for deciding whether to proceed with care planning and that they considered the development of care planning interventions for all RAPs triggered by the MDS. The care plan must reflect intermediate steps for each outcome objective if identification of those steps will enhance the resident's ability to meet his/her objectives. Facility staff will use these objectives to follow resident progress. Facilities may, for some residents, need to prioritize needed care. This should be noted in the clinical record or on the plan of care. The requirements reflect the facility's responsibility to provide necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well being, in accordance with the comprehensive assessment and plan of care. However, in some cases, a resident may wish to refuse certain services or treatments that professional staff believe may be indicated to assist the resident in reaching his or her highest practicable level of well-being. Desires of the resident should be documented in the clinical record. (See guidelines at §483.10(b)(4) for additional guidance concerning refusal of treatment.) Survey Procedures and Probes: §483.20(d)(1) o Does the care plan address the needs, strengths and preferences identified in the comprehensive resident assessment? o Is the care plan oriented toward preventing avoidable declines in functioning or functional levels? How does the care plan attempt to manage risk factors? Does the care plan build on resident strengths? o Do treatment objectives have measurable outcomes? o Does the care plan reflect standards of current professional practice? o Corroborate information regarding the resident's goals and wishes for treatment in the plan of care by interviewing residents, especially those identified as refusing treatment. o Determine whether the facility has provided adequate information to the resident so that the resident was able to make an informed choice regarding treatment. o If the resident has refused treatment, does the care plan reflect the facility's efforts to find alternative means to address the problem? For implementation of care plan, see §483.20(d)(3).

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C396	(2) A comprehensive care plan must be-- (i) Developed within 7 days after the completion of the comprehensive assessment; (ii) Prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and (iii) Periodically reviewed and revised by a team of qualified persons after each assessment.	Interpretive Guidelines: §483.20(d)(2) As used in this requirement, Ointerdisciplinary" means that professional disciplines, as appropriate, will work together to provide the greatest benefit to the resident. It does not mean that every goal must have an interdisciplinary approach. The mechanics of how the interdisciplinary team meets its responsibilities in developing an interdisciplinary care plan (e.g., a face-to-face meeting, teleconference, written communication) is at the discretion of the facility. The physician must participate as part of the interdisciplinary team, and may arrange with the facility for alternative methods, other than attendance at care planning conferences, of providing his/her input, such as one-to-one discussions and conference calls. The resident has the right to refuse specific treatments and to select among treatment options before the care plan is instituted. See §§483.10(d)(2) and (3) and 483.10(b)(4). The facility should encourage residents, surrogates, and representatives to participate in care planning, including encouraging attendance at care planning conferences if they so desire. Survey Procedures and Probes: §483.20(d)(2) 1. Was interdisciplinary expertise utilized to develop a plan to improve the resident's functional abilities? o For example, did an occupational therapist design needed adaptive equipment or a speech therapist provide techniques to improve swallowing ability? o Do the dietitian and the speech therapist determine, for example, the optimum textures and consistency for the resident's food that provide both a nutritionally adequate diet and effectively use oropharyngeal capabilities of the resident? o Is there evidence of physician involvement in development of the care plan (e.g., presence at care planning meetings, conversations with team members concerning the care plan, conference calls)? o In what ways do staff involve residents and families, surrogate, and/or representatives in care planning? o Do staff make an effort to schedule care plan meetings at the best time of the day for residents and their families? o Do facility staff attempt to make the process understandable to the resident/family? (Individual) Have you had concerns or questions about your care and brought them to the attention of facility staff? If yes, what happened as a result?

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C396 Cont.		Interpretive Guidelines: §483.20(d)(2)(iii) See §483.75(g)(2) for Qualified Person. Survey Procedures and Probes: §483.20(d)(2)(iii) Is the care plan evaluated and revised as the resident's status changes?
C397	(3) The services provided or arranged by the facility must-- (i) Meet professional standards of quality; and	Interpretive Guidelines: §483.20(d)(3)(i) The intent of this regulation is to assure that persons providing services are qualified to do so, that the resident's plan of care is implemented, and that those services provided meet professional standards of quality (in accordance with the following definition) and are provided by appropriate qualified persons (e.g., licensed, certified). "Professional standards of quality" means services that are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes may also be found in clinical literature. Possible reference sources for standards of practice include-- " Current manuals or textbooks on nursing, social work, physical therapy, etc. " Standards published by professional organizations such as the American Nurses' Association, the National Association of Social Work, the American Dietetic Association, the National Association of Activity Professionals, the American Medical Association, etc. " Clinical practice guidelines published by the Agency for Health Care Policy and Research. " Current professional journal articles. If a negative resident outcome is determined to be related to the facility's failure to meet professional standards, and the team determine a deficiency has occurred, it should be cited under the appropriate quality of care or other relevant requirement.
C398	(ii) Be provided by qualified persons in accordance with each resident's written plan of care.	

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C398 Cont.		Survey Procedures and Probes: §483.20(d)(3) Question only those practices which have a negative outcome or have a potential negative outcome. Ask the facility to produce references upon which the practice is based. o Do nurses notify physicians, as appropriate, and show evidence of discussions of acute medical problems? o Are residents with acute conditions who require intensive monitoring and hospital level treatments that the facility is unable to provide, promptly hospitalized? o Are there errors in the techniques of medication administration? o Is there evidence of assessment and care planning sufficient to meet the needs of newly admitted residents, prior to completion of the first comprehensive assessment and comprehensive care plan? o Are physicians' orders carried out, unless otherwise indicated by an advanced directive? o Can direct care giving staff describe the care, services and expected outcomes of the care they provide; have a general knowledge of the care and services being provided by other therapists; have an understanding of the expected outcomes of this care, and understand the relationship of these expected outcomes to the care they provide. Interpretive Guidelines: §483.(d)(3)(ii) If you find problems with quality of care, quality of life, or resident rights, are these problems attributable to the qualifications of the facility staff, or lack of, inadequate or incorrect implementation of the care plan?
C399	(e) Discharge summary. When the facility anticipates discharge a resident must have a discharge summary that includes-- (1) A recapitulation of the resident's stay; (2) A final summary of the resident's status to include items in paragraph (b)(2) of this section, at the time of the discharge that is	.Interpretive Guidelines: §483.20(e) The intent of this regulation is to ensure appropriate discharge planning and communication of necessary information to the continuing care provider. A post discharge plan of care for an anticipated discharge applies to a resident whom the facility discharges to a private residence, to another NF or SNF, or to another type of residential facility such as a board and care home or an intermediate care facility for mentally retarded individuals. A "post discharge plan of care" means the discharge planning process which includes: assessing continuing care needs and developing a plan designed to ensure the individual's needs will be met after discharge from the facility into the community. "Anticipates" means that the discharge was not an emergency discharge (e.g., hospitalization for an acute condition) or due to the resident's death.

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C399 Cont.	available for release to authorized persons and agencies, with the consent of the resident or legal representative; and (3) A post discharge plan of care that is developed with the participation of the resident and his or her family, which will assist the resident to adjust to his or her new living environment.	"Adjust to his or her living environment" means that the post discharge plan, as appropriate, should describe the resident's and family's preferences for care, how the resident and family will access these services, and how care should be coordinated if continuing treatment involves multiple care givers. It should identify specific resident needs after discharge such as personal care, sterile dressings, and physical therapy, as well as describe resident/care giver education needs to ensure the resident/care giver is able to meet care needs after discharge. Survey Procedures and Probes: §483.20(e) o Does the discharge summary have information pertinent to continuing care for the resident? o Is there evidence of discharge planning in the records of discharged residents who had an anticipated discharge or those residents to be discharged shortly (e.g., in the next 7-14 days)? o Do discharge plans address necessary post discharge care? o Has the facility aided the resident and his/her family in locating and coordinating post discharge services? o What types of predischarge preparation and education has the facility provided the resident and his/her family?
C400	**§483.25 Quality of Care.** Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. (i) Nutrition. Based on a resident's comprehensive assessment, the facility must ensure that a resident-- (1) Maintains acceptable parameters of nutritional status, such as body weight and	Interpretive Guidelines: §483.25(i) This corresponds to M.D.S., section L; M.D.S. 2.0 sections G, I, J, K and L when specified for use by the State. Parameters of nutritional status which are unacceptable include unplanned weight loss as well as other indices such as peripheral edema, cachexia and laboratory tests indicating malnourishment (e.g., serum albumin levels).

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C400 Cont.	protein levels, unless the resident's clinical condition demonstrates that this is not possible; and	Weight: Since ideal body weight charts have not yet been validated for the institutionalized elderly, weight loss (or gain) is a guide in determining nutritional status. An analysis of weight loss or gain should be examined in light of the individual's former life style as well as the current diagnosis.
C401	(2) Receives a therapeutic diet when there is a nutritional problem.	Suggested parameters for evaluating significance of unplanned and undesired weight loss are: Interval — Significant Loss — Severe Loss 1 month — 5% — Greater than 5% 3 months — 7.5% — Greater than 7.5% 6 months — 10% — Greater than 10% The following formula determines percentage of loss: % of body weight loss = usual weight - actual weight / usual weight x 100 In evaluating weight loss, consider the resident's usual weight through adult life; the assessment of potential for weight loss; and care plan for weight management. Also, was the resident on a calorie restricted diet, or if newly admitted and obese, and on a normal diet, are fewer calories provided than prior to admission? Was the resident edematous when initially weighed, and with treatment, no longer has edema? Has the resident refused food? Suggested laboratory values are: Albumin >60 yr.: 3.4 - 4.8 g/dl (good for examining marginal protein depletion) Plasma Transferrin >60 yr.:180 - 380 g/dl. (Rises with iron deficiency anemia. More persistent indicator of protein status.) Hemoglobin Males: 14-17 g/dl Females: 12-15 g/dl Hematocrit Males: 41 - 53 Females: 36 - 46 Potassium 3.5 - 5.0 mEq/L Magnesium 1.3 - 2.0 mEq/L Some laboratories may have different "normals". Determine range for the specific laboratory. Because some healthy elderly people have abnormal laboratory values, and because abnormal values can be expected in some disease processes, do not expect laboratory values to be within normal ranges for all residents. Consider abnormal values in conjunction with the resident's clinical condition and baseline normal values.

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C401 Cont.		NOTE: There is no requirement that facilities order the tests referenced above. Clinical Observations: Potential indicators of malnutrition are pale skin, dull eyes, swollen lips, swollen gums, swollen and/or dry tongue with scarlet or magenta hue, poor skin turgor, cachexia, bilateral edema, and muscle wasting. Risk factors for malnutrition are-- 1. Drug therapy that may contribute to nutritional deficiencies such as-- o Cardiac glycosides; o Diuretics; o Anti-inflammatory drugs; o Antacids (antacid overuse); o Laxatives (laxative overuse); o Psychotropic drug overuse; o Anticonvulsants; o Antineoplastic drugs; o Phenothiazines; o Oral hypoglycemics; 2. Poor oral health status or hygiene, eyesight, motor coordination, or taste alterations; 3. Depression or dementia; 4. Therapeutic or mechanically altered diet; 5. Lack of access to culturally acceptable foods; 6. Slow eating pace resulting in food becoming unpalatable, or in staff removing the tray before resident has finished eating; and 7. Cancer. Clinical conditions demonstrating that the maintenance of acceptable nutritional status may not be possible include, but are not limited to-- o Refusal to eat and refusal of other methods of nourishment; o Advanced disease (i.e., cancer, malabsorption syndrome); o Increased nutritional/caloric needs associated with pressure sores and wound healing (e.g., fractures, burns); o Radiation or chemotherapy; o Kidney disease, alcohol/drug abuse, chronic blood loss, hyperthyroidism;

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C401 Cont.		o Gastrointestinal surgery; and o Prolonged nausea, vomiting, diarrhea not relieved by treatment given according to accepted standards of practice. "Therapeutic diet" means a diet ordered by a physician as part of treatment for a disease or clinical condition, to eliminate or decrease certain substances in the diet, (e.g., sodium) or to increase certain substances in the diet (e.g., potassium), or to provide food the resident is able to eat (e.g., a mechanically altered diet). Survey Procedures and Probes §483.25(i) Determine if residents selected for a comprehensive review, or focused review as appropriate, have maintained acceptable parameters of nutritional status. Where indicated by the resident's medical status, have clinically appropriate therapeutic diets been prescribed? For sampled residents whose nutritional status is inadequate, do clinical conditions demonstrate that maintenance of inadequate nutritional status was unavoidable-- o Did the facility identify factors that put the resident at risk for malnutrition? o Identify if resident triggered RAPs for nutritional status, ADL functional/rehabilitation potential, feeding tubes, psychotropic drug use, and dehydration/fluid balance. Consider whether the RAPs were used to assess the casual factors for decline, potential for decline or lack of improvement. o What routine preventive measures and care did the resident receive to address unique risk factors for malnutrition (e.g., provision of an adequate diet with supplements or modifications as indicated by nutrient needs)? o Were staff responsibilities for maintaining nutritional status clear, including monitoring the amount of food the resident is eating at each meal and offering substitutes? o Was this care provided consistently? o Were individual goals of the plan of care periodically evaluated and if not met, were alternative approaches considered or attempted?
C402	**§483.45 Specialized rehabilitative services.**	

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C402 Cont.	(a) Provision of services. If specialized rehabilitative services such as, but not limited to, physical therapy, speech-language pathology, occupational therapy, and mental health rehabilitative services for mental illness and mental retardation, are required in the resident's comprehensive plan of care, the facility must-- (1) Provide the required services; or (2) Obtain the required services from an outside resource (in accordance with §483.75(h) of this part from a provider of specialized rehabilitative services.	The intent of this regulation is to assure that residents receive necessary specialized rehabilitative services as determined by the comprehensive assessment and care plan, to prevent avoidable physical and mental deterioration and to assist them in obtaining or maintaining their highest practicable level of functional and psychosocial well being. "Specialized rehabilitative services" are differentiated from restorative services which are provided by nursing staff. Specialized rehabilitative services are provided by or coordinated by qualified personnel. Specialized rehabilitative services are considered a facility service and are, thus, included within the scope of facility services. They must be provided to residents who need them even when the services Are not specifically enumerated in the State plan. No fee can be charged a Medicaid recipient for specialized rehabilitative services because they are covered facility services. A facility is not obligated to provide specialized rehabilitative services if it does not have residents who require these services. If a resident develops a need for these services after admission, the facility must either provide the services, or, where appropriate, obtain the service from an outside resource. For a resident with MI or MR to have his or her specialized needs met, the individual must receive all services necessary to assist the individual in maintaining or achieving as much independence and self determination as possible. They are-- "Specialized services for MI or MR" refers to those services to be provided by the State which can only be delivered by personnel or programs other than those of the NF (e.g., outside the NF setting), because the overall level of NF services is not as intense as necessary to meet the individuals needs. The Preadmission Screening and Annual Resident Review (PASARR) report indicates specialized services required by the resident. The State is required to list those services in the report, as well as provide or arrange for the provision of the services. If the State determines that the resident does not require specialized services, the facility is responsible to provide all services necessary to meet the resident's mental health or mental retardation needs. "Mental health rehabilitative services for MI and MR" refers to those services of lesser frequency or intensity to be implemented by all levels of nursing facility staff who come into contact with the resident who is mentally ill or who has mental retardation. These services are necessary regardless of

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C402 Cont.		whether or not they are required to be subject to the PASARR process and whether or not they require additional services to be provided or arranged for by the State as specialized services. The facility should provide interventions which complement, reinforce and are consistent with any specialized services (as defined by the resident's PASARR) the individual is receiving or is required to receive by the State. The individual's plan of care should specify how the facility will integrate relevant activities throughout all hours of the individual's day at the NF to achieve this consistency and enhancement of PASARR goals. The surveyor should see competent interaction by staff at all times, in both formal and informal settings in accordance with the individual's needs. Mental health rehabilitative services for MI and MR may include, but are not limited to-- o Consistent implementation during the resident's daily routine and across settings, of systematic plans which are designed to change inappropriate behaviors; o Drug therapy and monitoring of the effectiveness and side effects of medications which have been prescribed to change inappropriate behavior or to alter manifestations of psychiatric illness; o Provision of a structured environment for those individuals who are determined to need such structure (e.g., structured socialization activities to diminish tendencies toward isolation and withdrawal); o Development, maintenance and consistent implementation across settings of those programs designed to teach individuals the daily living skills they need to be more independent and self determining including, but not limited to, grooming, personal hygiene, mobility, nutrition, vocational skills, health, drug therapy, mental health education, money management, and maintenance of the living environment; o Crisis intervention services; o Individual, group, and family psychotherapy; o Development of appropriate personal support networks; and o Formal behavior modification progress. Survey Procedures and Probes §483.45(a)(1)(2) For sampled residents, whose comprehensive assessment indicates physical, psychosocial, and/or communications rehabilitation potential (See M.D.S. Sections E, C, G, H, in version 2.0, sections G, C, F, E. References to version 2.0 of the M.D.S. are effective when the State respecifies its RAI), observe for unmet needs for rehabilitative services. Determine the extent of follow through with the comprehensive care plan using probes outlined below. Verify from the chart that the resident is receiving frequency and type of therapy as outlined in the care plan.

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C402 Cont.		1. PHYSICAL THERAPY o What did the facility do to improve the resident's muscle strength? The resident's balance? o What did the facility do to determine if an assistive device would enable the resident to reach or maintain his/her highest practicable level of physical function? o If the resident has an assistive device, is he/she encouraged to use it on a regular basis? o What did the facility do to increase the amount of physical activity the resident could do (for example, the number of repetitions of an exercise, the distance walked)? o What did the facility do to prevent or minimize contractures, which could lead to decreased mobility and increased risk of pressure ulcer occurrence? 2. OCCUPATIONAL THERAPY o What did the facility do to decrease the amount of assistance needed to perform a task? o What did the facility do to decrease behavioral symptoms? o What did the facility do to improve gross and fine motor coordination? o What did the facility do to improve sensory awareness, visual-spatial awareness, and body integration? o What did the facility do to improve memory, problem solving, attention span, and the ability to recognize safety hazards? 3. SPEECH, LANGUAGE PATHOLOGY o What did the facility do to improve auditory comprehension such as understanding common, functional words, concepts of time and place, and conversation? o What did the facility do to improve speech production? o What did the facility do to improve expressive behavior such as the ability to name common, functional items? o What did the facility do to improve the functional abilities of residents with moderate to severe hearing loss who have received an audio logic evaluation? For example, did the facility instruct the resident how to effectively and independently use environmental controls to compensate for hearing loss such as eye contact, preferential seating, use of the better ear? o For the resident who cannot speak, did the facility assess for a communication board or an alternate means of communication?

PART III-INTERPRETIVE GUIDELINES-CRITICAL ACCESS HOSPITALS

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C402 Cont.		4. REHABILITATIVE SERVICES FOR MI AND MR N What did the facility do to decrease incidents of inappropriate behaviors, for individuals with MR, or behavioral symptoms for persons with MI? To increase appropriate behavior? o What did the facility do to identify and treat the underlying factors behind tendencies toward isolation and withdrawal? o What did the facility do to develop and maintain necessary daily living skills? o How has the facility modified the training strategies it uses with its residents to account for the special learning needs of its residents with MI or MR? o Questions to ask individuals with MI or MR-- o Who do you talk to when you have a problem or need something? o What do you do when you feel happy? Sad? Can't sleep at night? o In what activities are you involved, and how often?
C403	(b) Qualifications. Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.	Interpretive Guidelines §483.45(b) Specialized rehabilitative services are provided for individual's under a physician's order by a qualified professional. Once the assessment for specialized rehabilitative services is completed, a care plan must be developed, followed, and monitored by a licensed professional. Once a resident has met his or her care plan goals, a licensed professional can either discontinue treatment or initiate a maintenance program which either nursing or restorative aides will follow to maintain functional and physical status. "Qualified personnel" means that professional staff are licensed, certified or registered to provide specialized therapy/rehabilitative services in accordance with applicable State laws. Health rehabilitative services for MI and MR must be implemented consistently by all staff unless the nature of the services is such that they are designated or required to be implemented only be licensed or credentialed personnel. Survey Procedures and Probes §483.45(b) Determine if there are any problems in quality of care related to maintaining or improving functional abilities. Determine if these problems are attributable in part to the qualifications of specialized rehabilitative services staff.

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C403 Cont.		Determine from the care plan and record that rehabilitative services are provided under the written order of a physician and by qualified personnel. If a problem in a residents rehabilitative care is identified that is related to the qualifications of the care providers, it may be necessary to validate the care providers qualification. If the facility does not employ professional staff who have experience working directly with or designing training or treatment programs to meet the needs of individuals with MI or MR, how has the facility arranged for the necessary direct or staff training services to be provided?
C404	**§483.55 Dental services**. The facility must assist residents in obtaining routine and 24 hour emergency dental care.	Interpretive Guidelines §483.55 This requirement makes the facility directly responsible for the dental care needs of its residents. The facility must ensure that a dentist is available for residents (i.e., employ a staff dentist or have a contract (arrangement) with a dentist to provide services). For Medicare and private pay residents, facilities are responsible for having the services available, but they may impose an additional charge for the services. For all residents of the facility, if they are unable to pay for needed dental services, the facility should attempt to find alternative funding sources or alternative service delivery systems so that the resident is able to maintain his/her highest practicable level of well being. The facility is responsible for selecting a dentist who provides dental services in accordance with professional standards of quality and timeliness under §483.75(h)(2).
C405	(a) Skilled nursing facilities. A facility-- (A) Must provide or obtain from an outside resource, in accordance with §483.75(h) of this part, routine and emergency dental services to meet the needs of each resident; (2) May charge a Medicare resident an additional amount for routine and emergency dental services;	

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C406	(3) Must if necessary, assist the resident-- (I) In making appointments; and (ii) By arranging for transportation to and from the dentist's office; and (4) Promptly refer residents with lost or damaged dentures to a dentist. NOTE: §483.55(b) does not apply to CAHs.	"Routine dental services" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures). "Emergency dental services" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity, appropriately treated by a dentist that requires immediate attention. "Prompt referral' means, within reason, as soon as the dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time, but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing the dentures. Survey Procedures and Probes §483.55 Do residents selected for comprehensive or focused reviews, as appropriate, with dentures, use them? Are residents missing teeth and may be in need of dentures? Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene? Are resident's dentures intact? Properly fitted?